Interventionen zur Reduktion von Medikationsfehlern in der Pflege von älteren Patient/-innen im Spital und Pflegeheim

eine Literaturübersicht

Bachelorarbeit

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ABSTRACT / ZUSAMMENFASSUNG

Hintergrund: Medikationsfehler sind ein immer wieder kehrendes Problem. Sie werden durch verschieden Akteure während des ganzen Medikationsprozesses verursacht und haben unterschiedliche Ursachen. Medikationsfehler können zu gesundheitlichen Schäden oder gar zum Tode führen. Sie führen zu zusätzlichen Kosten im Gesundheitswesen. Besonders vulnerabel sind dabei ältere Personen. Die Polymedikation im Alter sowie der veränderte Metabolismus erhöhen das Risiko eines unerwünschten Medikationsergebnisses. Um die negativen Folgen so gering wie möglich zu halten, sind daher evidenzbasierte Interventionen gefragt. Dabei sollte der Fokus bei den Pflegenden liegen, da diese die meisten Schritte des Medikationsprozesses ausführen.

Methode: Die Fragestellung «Welche Interventionen können zur Reduktion von Medikationsfehlern in der Pflege von Patient/-innen ab dem 64.Lebensjahr im Spital und Pflegeheim beitragen?» wurde anhand einer Literaturübersicht beantwortet. Dazu wurde eine Literaturrecherche in den Datenbanken PubMed und CINAHL durchgeführt. Die Studien wurden kritisch beurteilt, analysiert und die Ergebnisse anschliessend tabellarisch wie narrativ dargestellt.

Ergebnisse: Es wurden acht Studien mit verschiedenen Designs eingeschlossen. Die Interventionen wurden in vier Kategorien eingeteilt: Schulungen, Barcode Scanning, Dokumente zum Abgleich und systemischer Ansatz. Die Anzahl an Medikationsfehler konnten durch den systemischen Ansatz, durch das Barcode Scanning, durch die Beers-Liste (Dokument zum Abgleich) gesenkt werden. Schulungen zum Thema der schädigenden Medikation sowie zum Mörsern von Medikamenten zeigten ebenfalls signifikante Erfolge.

Schlussfolgerungen: Es sollten vermehrt randomisierte Kontrollstudien realisiert werden, in denen die Interventionen spezifisch auf Pflegende ausgelegt sind. Dabei sollte der Aspekt der Transition berücksichtigt werden sowie die Durchführung in mehreren Institutionen. Die Interventionen müssen jedoch meist noch an das Schweizer Gesundheitswesen angepasst werden.

Schlüsselbegriffe: Medikationsfehler, unangemessene Medikation, unerwünschte Medikamentennebenwirkungen, Interventionen, Pflegeinterventionen

1 EINLEITUNG

Im Folgenden wird die Problemstellung, die Fragestellung und das Ziel erläutert.

1.1 Problemstellung

Aly (2014) definiert Medikationsfehler als Abweichen vom optimalen Medikationsprozess. Dieses Abweichen kann zu unerwünschten Ergebnissen bei Patient/-innen führen. Dazu gehören zum Beispiel allergische Reaktionen, diverse Nebenwirkungen der Medikamente oder Schädigungen des Gewebes aufgrund falscher Medikamentenform oder -dosis. Fehler können während des ganzen Medikationsprozesses geschehen und von jeder beteiligten Person versursacht werden. Medikationsfehler sind folglich ein interdisziplinäres Problem, welche trotz der in Artikel 3 des Heilmittelgesetzes genannten Sorgfaltspflicht vorkommen (Bundesversammlung der Schweizerischen Eidgenossenschaft, 2014a). Dies schliesst Ärzte/-innen, Apotheker/-innen und Pflegende oder andere Angehörige eines Gesundheitsberufes sowie Patient/-innen und deren Angehörige mit ein (Aly, 2014). Medikationsfehler können bei der Verordnung, der Vorbereitung, der Verteilung, der Anwendung und beim Monitoring (Kontrolle des Therapieerfolgs, abfragen von Symptomen) geschehen (Fishman, 2015).

Die Gründe von Medikationsfehlern sind breit gefächert. Aufgrund altersdemographischen Veränderungen wird die Pflege in naher Zukunft bei der älteren Population einen noch grösseren Stellenwert in der Gesellschaft einnehmen (Bundesamt für Statistik, 2016, 2017). Mit steigendem Alter verändert sich die Pharmakokinetik und -dynamik. Zeitgleich erhöht sich das Risiko der Multimorbidität und somit auch das der Polypharmazie (Schmid, Bannert, & Studer-Flury, 2011). Zu jedem Arzneimittel gibt es unzählige unerwünschte Nebenwirkungen und Interaktionen mit anderen Medikamenten. Durch diese medikamentenbedingten Probleme wird die sichere Medikation zusätzlich erschwert (Fishman, 2015). Organisationsbezogene Faktoren wie der Personalschlüssel, Zeitmangel oder interne Abläufe können ebenfalls zu Medikationsfehlern führen. Aber auch menschliche Ursachen wie Müdigkeit und Unachtsamkeit können Fehler provozieren (World Health Organization, 2016, 2017).

Medikationsfehler führen nicht nur zu physischen und psychischen Konsequenzen, sondern auch zu finanziellen. Weltweit werden pro Jahr etwa 42 Milliarden US-Dollars an Unkosten fällig aufgrund von Medikationsfehlern (World Health Organization, 2017). Die Zahlen in der Schweiz werden auf 1.6 Milliarden Franken im Spitalsetting pro Jahr geschätzt (Schaad, 2001). Neuere und genauere Zahlen für die Schweiz sind nicht verfügbar (Bundesversammlung der Schweizerischen Eidgenossenschaft, 2014b). Es wird geschätzt, dass in Deutschland durch vermeidbare Medikationsfehler 816 Millio-

nen bis 1,3 Milliarden Euro pro Jahr eingespart werden könnten (Aly, 2014). Pro Jahr erleiden etwa 5.2% der Patient/-innen unerwünschten Outcome (Meyer-Massetti & Conen, 2012). Dies kann zu einem Wiedereintritt in das Spital, einer Verlängerung der Aufenthaltsdauer bei bereits hospitalisierten Patient/-innen und im schlimmsten Fall zum Tode führen (Bates et al., 1995; Hardmeier et al., 2004; Lazarou, Pomeranz, & Corey, 1998; Zegers et al., 2009). Eine Studie aus dem Jahr 1999 zeigt auf, dass zum damaligen Zeitpunkt 6.4% der Notfalleintritte auf Medikationsfehler zurück zu führen waren (Lepori, Perren, & Marone, 1999). Eine niederländische Studie geht davon aus, dass 39.4% der Medikationsfehler vermeidbar wären (Zegers et al., 2009). Besonders oft entstehen solche Fehler an Schnittstellen, wo Patient/-innen ein System verlassen und in ein nächstes übertreten. Dieser Schnittstellenproblematik ist sich auch die Stiftung «Patientensicherheit Schweiz» bewusst und hat daraufhin das Pilotprojekt progress! «sichere Medikation» lanciert (Patientensicherheit Schweiz, 2017a). Auch der Bund ist nicht inaktiv geblieben und unterstützt dieses und andere Programme im Sinne der Qualitätsstrategie im schweizerischen Gesundheitswesen, bekannt als Gesundheit 2020 (Bundesamt für Gesundheit, 2017). Die Weltgesundheitsorganisation (WHO) sieht ebenfalls Handlungsbedarf bei der sicheren Medikation. Im März 2017 lancierte die WHO eine globale Initiative zur Risikoreduktion von Medikationsfehlern. Ihr Ziel ist es, Medikationsfehler innert fünf Jahren um die Hälfte zu reduzieren (World Health Organization, 2017).

Aus den oben genannten internationalen Studien lässt sich schliessen, dass Medikationsfehler eine globale Herausforderung sind (World Health Organization, 2016). Die Zahlen und Fakten belegen die Wichtigkeit dieses Themas. Pflegende können grossen Einfluss auf die Aspekte der Vorbereitung, Verteilung, Anwendung und Monitoring nehmen. Die Mehrheit der älteren Patient/-innen befinden sich in einem stationär betreuten Setting wie Spitäler und Pflegeheime (Füglister-Dousse, Dutoit, & Pellegrini, 2015). In diesen Bereichen haben die Pflegenden grosse Kontrolle über den Medikationsprozess, zum Beispiel bei der Vorbereitung, der Verabreichung und des Monitorings. Aufgrund nicht ausreichender Studien in den einzelnen Settings wurden Spital wie auch Pflegeheim in die Fragestellung aufgenommen. Die Autorinnen haben sich hierfür entschieden, da die Interventionen die Pflege selbst betreffen und nicht die Patient/-innen. Die Autorinnen sind sich jedoch auch bewusst, dass auch im Spitexsetting Medikationsfehler auftreten können. Aufgrund von fehlender Kontrolle wären besonders hier präventive Interventionen sinnvoll. Das Spitexsetting wurde schlussendlich aufgrund mangelnder Studien und Daten nicht in die Fragestellung aufgenommen.

Eine fundierte wissenschaftliche Recherche kann der Praxis helfen, die Medikationsfehler signifikant zu senken. Dadurch können Kosten und Zeit gespart, die Patientensicherheit verbessert und somit das Wohlergehen der Gesellschaft gestärkt werden. Um der Gesundheit Willen, wie auch der steigenden Gesundheitskosten muss aktiv gegen Medikationsfehler angegangen werden. Dies nicht erst in zehn Jahren, sondern bereits heute.

1.2 Fragestellung

Anhand des PICO-Schemas konnte folgende Fragestellung erarbeitet werden:

- P: Patient/-innen ab dem 64. Lebensjahr
- I: Interventionen
- C: -
- O: Reduktion der Medikationsfehler

Welche Interventionen können zur Reduktion von Medikationsfehlern in der Pflege von Patient/-innen ab dem 64.Lebensjahr im Spital und Pflegeheim beitragen?

1.3 Ziel

Das Ziel der Autorinnen ist es, mit dieser Arbeit Interventionen zu beschreiben und zu diskutieren, mit denen Medikationsfehler reduziert werden können. Die Literaturübersicht soll allen Interessenten/-innen aus der Praxis dienlich sein. Die Übertragbarkeit und die Anwendungsmöglichkeiten dieser Interventionen im Schweizer Gesundheitswesen wird kritisch hinterfragt.

2 THEORETISCHER RAHMEN

Zum besseren Verständnis des Themas werden im nachfolgenden Teil die theoretischen Grundlagen zu Medikationsfehlern erläutert. Es werden ebenfalls wichtige Begriffe definiert.

2.1 Definitionen

Die Arten an Medikationsfehler sind vielfältig und vielschichtig. Oftmals gibt es für denselben Begriff unterschiedliche Formulierungsformen oder Definitionen. Viele der englischsprachigen Begriffe werden in der deutschen Sprache kaum benutzt, bzw. gibt es keine geläufigen Übersetzungen. Die Autorinnen halten es daher für sinnvoll, die wichtigsten Begriffe genauer zu definieren. Dies erfolgte über Definitionen seitens der Autor/-innen der einzelnen Studien, wie auch über eine Recherche in der Fachliteratur.

Medication error, übersetzt als Medikationsfehler: Ein Medikationsfehler wird definiert als eine Abweichung vom optimalen Medikationsprozess. Dieses Abweichen kann

zu unerwünschten Folgen führen. Medikationsfehler werden als vermeidbar eingestuft, können in allen Stadien vorkommen (z.B. Verschreibung, Bestellkommunikation, Produktkennzeichnung, Verpackung, Zubereitung, Abgabe, Verteilung, Verabreichung, etc.) und können von allen beteiligten Personen begangen werden (Aly, 2014; National Coordinating Council for Medication Error Reporting and Prevention, 2018).

Drug related problem, übersetzt als medikamentenbedingtes Problem: Medikamentenbedingte Probleme sind Auswirkungen von Medikamenten, die auftreten können. Manche davon können unbedeutend sein, andere können zur Hospitalisation oder zum Tode führen (Bergqvist, Ulfvarson, & Andersén Karlsson, 2009). Die medikamentenbedingten Probleme werden in intrinsische und extrinsische Toxizität eingeteilt. Die intrinsische Toxizität wird durch die Interaktion des Wirkstoffes mit dem Körper ausgelöst und ist daher als Synonym der unerwünschten Medikamentennebenwirkungen zu verstehen. Die extrinsische Toxizität bezieht sich auf die Probleme, die durch den Umgang mit dem Medikament verursacht wird, entweder durch Gesundheitsfachpersonen oder durch Patient/-innen (van den Bemt & Egberts, 2007).

Adverse drug reaction/event, übersetzt als unerwünschte Medikamentennebenwirkung: Als unerwünschte Nebenwirkung werden die Auswirkungen von Medikamenten beschrieben, die nicht beabsichtigt, aber schädlich sind (World Health Organization, 2002). Sie werden verursacht durch die Interaktion des Arzneimittelstoffs mit dem menschlichen Biosystem (van den Bemt & Egberts, 2007).

Inappropiate drug/medication, übersetzt als unangemessene Medikation: Als unangemessene Medikation werden Medikamente beschrieben, bei denen die Risiken die Vorteile überwiegen, besonders wenn sicherere Alternativen vorhanden wären (Pitkälä et al., 2014).

Medication history taking, übersetzt als Medikamentenabstimmung oder Medikationsabgleich: Bei der Medikamentenabstimmung, bzw. Medikationsabgleich werden die in der Vergangenheit und Gegenwart genommenen Medikamente genauestens erfragt und eine Liste erstellt (Henneman, Tessier, Nathanson, & Plotkin, 2014; Patiententsicherheit Schweiz, 2017).

Potential harmful medication, übersetzt als potentiell schädigende Medikamente: Potentiell schädigende Medikamente werden im Artikel von Pitkälä et al. (2014) mit potentiell unangemessenen Medikamenten gleichgesetzt. Definition von unangemessener Medikation: siehe oben (Pitkälä et al., 2014).

Medication administration error, übersetzt als Medikamentenabgabefehler: Als Medikamentenabgabefehler werden Fehler definiert, die durch Ärzte/-innen und Pflege-

fachpersonal bei der Abgabe an Patient/-innen gemacht werden. Sie lassen sich in die Unterkategorien falsche Zeit, falsche Vorbereitung, falsche Dosis, falsche Applikationsart und falsche Technik einteilen. Zusätzlich werden auch nicht verschriebene Medikamente, die trotzdem abgeben wurden, wie auch nicht verabreichte Medikamente als Medikamentenabgabefehler gezählt (van den Bemt & Egberts, 2007).

2.2 Arten der Medikationsfehler

Im Nachfolgenden werden die Medikationsfehlerarten genauer beschrieben.

Das National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) definiert Medikationsfehler als «jedes vermeidbare Ereignis, das zu einer unangemessenen Medikationsverwendung oder zu einer Schädigung des Patienten führen kann, soweit die Medikation unter Aufsicht des medizinischen Fachpersonals, Patienten oder Konsumenten steht» (National Coordinating Council for Medication Error Reporting and Prevention, 2018). Diese Definition wird auch von der Weltgesundheitsorganisation (WHO) verwendet und anerkannt (World Health Organization, 2017).

Nach Meyer-Massetti und Conen (2012) können Medikationsfehler auf allen Stufen der Medikationstherapie stattfinden. Die Fehler können von jeder beteiligten Person begangen werden, seien dies nun Ärzte/-innen, Pflegefachpersonen oder die Patient/-innen und ihre Angehörigen selbst (Kulick & Jaehde, 2017).

Kulick und Jaehde (2017) beschreiben acht mögliche Fehlerquellen. Wenn man dem Medikationsprozess von Anfang bis Ende folgt, so können die Fehler bereits bei der Diagnosestellung geschehen. Dies hat anschliessend Auswirkungen auf die Medikationsauswahl. Bei den Verordnungen, bzw. der Information können ebenfalls Fehler geschehen. Dies schliesst ungeeignete Medikamente, deren Dosis aber auch eine fehlerhafte Indikation mit ein. Weitere Fehlerquellen sind die Überbringung (nicht einlösen des Rezepts) wie auch die Selbstmedikation. Werden Medikamenteninteraktionen oder Kontraindikationen nicht wahrgenommen, fällt dies unter die Fehlerquelle der Medikationsanalyse. Eine inkorrekte Information bzw. Abgabe der Medikamente kann ebenfalls zu Fehlern führen. Hier wird besonders auf die Medikamentenabgabe an die richtigen Patient/-innen hingewiesen, aber auch auf die Vorbereitung und Verteilung. Die inkorrekte Handhabung der 5R-Regeln (richtige/-r Patient/-in, richtiges Medikament, richtige Dosis, richtige Zeit, richtige Applikationsart) fallen unter die Fehlerquelle der Abgabe wie auch unter die Anwendung. Unter einer falschen Anwendung wird die inkorrekte Galenik, Über- oder Unterdosierung, wie auch falsche Einnahmezeiten verstanden. Die Fehlerquelle des Monitorings bezieht sich auf mangelnde Überwachung des Therapie-

erfolgs (Kulick & Jaehde, 2017; Meyer-Massetti & Conen, 2012; Schmid et al., 2011). Einnahmefehler der Patient/-innen werden in der Regel durch das Ausbleiben der erwünschten Wirkung oder im Gespräch aufgedeckt. Der Grund weshalb dies geschieht, liegt meist darin, dass den Patient/-innen ungenügende Informationen zur Verfügung stehen (Beyer & Gerlach, 2003).

Nicht jeder Medikationsfehler führt zu einem unerwünschten Ereignis. Teilweise tritt kein Schaden auf, obwohl ein falsches Medikament oder eine falsche Dosierung verwendet wurde (Kulick & Jaehde, 2017).

2.3 Human Error Modell nach James Reason

James Reason gehört zu den bekanntesten Autoren, die sich mit dem Thema des Sicherheits- und Fehlermanagements auseinandersetzen. Seine Arbeit war nicht nur wegweisend für die Flugsicherheit sondern auch für die Patientensicherheit und mit ihr, auch für die Medikationssicherheit (Peltomaa, 2012).

Menschliche Fehler können laut Reason (2000) in zwei Kategorien von Ursachen eingeteilt werden – in den menschlichen und dem systemischen Ansatz. Je nach Ansatz werden unterschiedliche Schlussfolgerungen und Interventionen abgeleitet (Reason, 2000).

Beim menschlichen Ansatz wird oftmals davon ausgegangen, dass Unaufmerksamkeit, mangelnde Motivation, Nachlässigkeit und Rücksichtslosigkeit der Ursprung aller Fehler sind. Die Gegenmassnahmen, um diese Fehler zu beseitigen, beschränken sich meist auf die Reduzierung unerwünschter Schwankungen im menschlichen Verhalten. Dies wird mit Postern, Disziplinarmassnahmen, Drohungen, Beschuldigungen und Schmähungen erreicht. Individuen wegen ihrer gemachten Fehler zu beschuldigen ist, psychologisch und gesellschaftlich gesehen, einfacher und zufriedenstellender als Institutionen und ihre Abläufe als Sündenbock oder Fehlerquelle darzustellen (Peltomaa, 2012; Reason, 1995, 2000). Der systemische Ansatz geht davon aus, dass menschliche Fehler jederzeit und überall auftreten können, egal in welcher Position oder Situation. Beim menschlichen Ansatz werden Fehler als Ursache angesehen, beim systemischen als Konsequenzen. Fehler sind die Konsequenzen von organisatorischen Abläufen und der Umgebung, in der die Fehler stattgefunden haben. Ergo muss nicht das menschliche Verhalten verändert werden, sondern die Konditionen unter denen die Menschen arbeiten. Oftmals treten dieselben Fehler immer wieder auf. Daher sollte bei einem Fehlverhalten nicht primär das Wer erfragt werden, sondern vielmehr nach dem Wieso, Warum und Wie. Aus diesen gewonnenen Erkenntnissen können massge-

schneiderte Massnahmen zur Fehlerreduzierung abgeleitet werden (Peltomaa, 2012; Reason, 2000).

Zu diesem systemischen Ansatz entwickelte Reason das Schweizer Käse Modell. Um Fehler zu vermeiden, nehmen Sicherheitsvorkehrungen, Barrieren und Abwehrmassnahmen auf verschiedenen Ebenen eine zentrale Rolle ein. In einer idealen Welt wäre jede Barriere und Sicherheitsvorkehrung intakt. In der Realität jedoch bilden, schliessen und verändern sich die Löcher in den verschiedenen Barrieren (=Käsescheiben) stetig. Fehler im systemischen Ansatz geschehen erst dann, wenn die Löcher in vielen Schichten kurzzeitig aneinandergereiht sind, und so die Wahrscheinlichkeit einer Fehlerquelle erhöhen (Peltomaa, 2012; Reason, 2000).

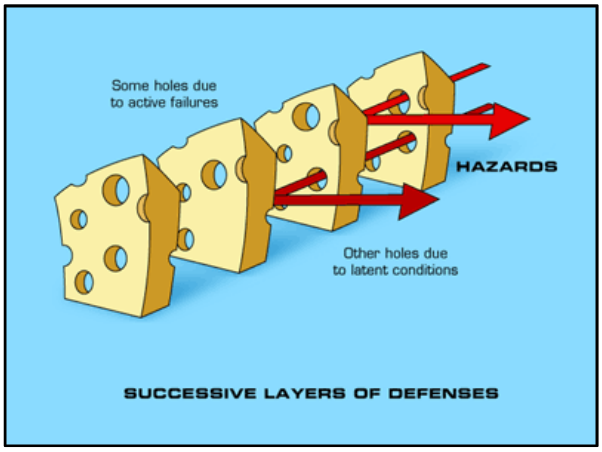

Abbildung 1: Schweizer Käse Modell, erfolgreiche Abwehr (Schwartz, 2016)

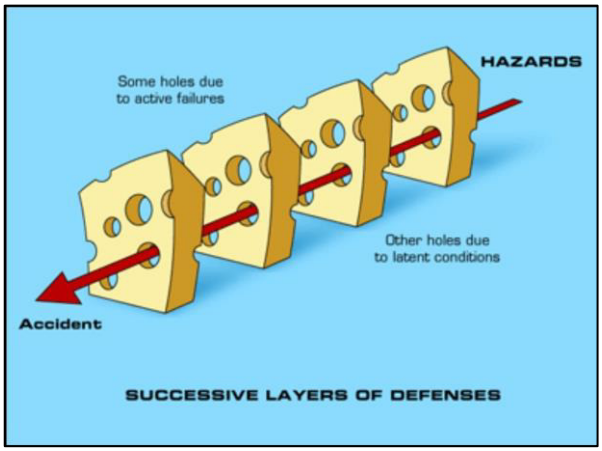

Abbildung 2: Schweizer Käse Modell, nicht erfolgreiche Abwehr (Reason, 2000)

Die Löcher in den Schichten werden laut Reason (2000) in zwei Fehlerquellen eingeteilt: aktive Fehler und latente Konditionen. Aktive Fehler werden als Verstösse gegen die Sicherheitsvorkehrungen gesehen, die von Personen verübt werden, die mit den Patient/-innen in direktem Kontakt stehen. Diese Fehler haben meist nur einen kurzzeitigen Effekt auf einzelne Sicherheitsbarrieren. Latente Konditionen, oder auch latente

Zustände genannt, sind die unausweichlichen Krankheitserreger eines Systems. Sie hängen meist mit strategischen Entscheidungen zusammen und können das System provozieren (z.B. durch Zeitdruck, Unterbesetzung, Unterqualifizierung, etc.) und zusätzlich ein langanhaltendes Loch in die Barrieren (=Käseschichten) fressen (z.B. durch fehlendes Vertrauen, schlechte Arbeitsbedingungen, etc.). Im Gegensatz zu den aktiven Fehlern, welche oft schwer vorhersehbar sind, können latente Konditionen identifiziert und behoben werden, bevor ein unerwünschtes Ereignis eintritt. Dies führt zum proaktiven Risikomanagement (Reason, 1990, 1995).

Auf das Gesundheitswesen bezogen, bedeutet dies, dass Kontrollen an mehreren Punkten eines Ablaufes entscheidend für die Sicherheit der Patient/-innen sind. Die Kontrollpunkte sollten nicht nur auf eine einzelne Pflegefachperson bezogen sein, sondern auch das interdisziplinäre Team, deren Aufgabenablauf, die Arbeitsumgebung und die Institution selbst betreffen (Peltomaa, 2012). Eines der besten Beispiele für eine optimierte Sicherheit mit diversen Kontrollpunkten im Schweizer Gesundheitswesen ist die Checkliste «sichere Chirurgie», bei der die Identifikation der Patient/-innen sowie Eingriffsart an allen Checkpoints durch verschiedenen Akteure immer wieder überprüft wird (Patientensicherheit Schweiz, 2017). Dabei sind Pflegefachpersonen der jeweiligen Abteilungen involviert sowie Anästhesie- wie Operationspersonal und die behandelnden Ärzte/-innen. Das Thema der Medikationssicherheit ist der nächste Schritt der von der Stiftung Patientensicherheit angegangen wird.

2.4 Progress! sichere Medikation

Das Pilotprojekt progress! «sichere Medikation» wurde von der Stiftung Patientensicherheit Schweiz lanciert. Es gehört der Qualitätsstrategie des Bundes zur schweizerischen Gesundheitspolitik an (Patientensicherheit Schweiz, 2017).

An Behandlungsschnittstellen besteht immer ein erhöhtes Risiko für Medikationsdiskrepanzen, mit möglichen folgenschweren Auswirkungen auf das Patientenwohl. Ein Teilziel des Pilotprojekts «sichere Medikation» war es, durch den systematischen Medikationsabgleich in Spitälern eine strukturierte Erfassung aller Medikamente zu erlangen und um diese bei Verlegungen oder Austritten konsequent abgleichen zu können. Da der Effekt dieser Intervention bereits durch diverse Studien bewiesen wurde, fiel der Fokus dieses Projekts vielmehr auf die Machbarkeit im Schweizer Gesundheitswesen (Patiententsicherheit Schweiz, 2017).

Acht, der anfangs neun Pilotspitälern (ein Drop Out wegen Ressourcenmangel), beschrieben ihre Erwartungen als erreicht oder erfüllt, gaben aber auch an, dass es aufgrund der zeit- und ressourcenintensiven Methode eher unwahrscheinlich sei, dass das

Programm weitergeführt werde (Patiententsicherheit Schweiz, 2017). Die Intervention sieht drei Schritte vor; bei Eintritt die bestmöglichste Medikationsanamnese zu erstellen (idealerweise anhand zweier Informationsquellen, z.B. Patientengespräch wie auch Angehörigengespräch), anschliessend die Eintrittsverordnungen zu erstellen und diese als letzten Schritt durch eine Zweitperson prüfen zu lassen. Bei einer internen Verlegung wird die Verordnung durch eine/-n Arzt oder Ärztin erstellt und idealerweise durch eine Zweitperson wie eine/-n Apotheker/-innen geprüft. Beim Austritt wird eine Liste der Austrittsmedikation erstellt, optional durch eine Zweitperson mit Fachwissen geprüft und anschliessend dem Patient/-innen erklärt. Zusätzlich sollte der Leistungserbringer (z.B. Apotheke) von den behandelnden Ärzten/-innen über die Medikation informiert werden (Patientensicherheit Schweiz, 2017b).

Das System verspricht eine hohe Patientensicherheit, braucht gleichzeitig aber auch die Unterstützung des Managements. Der systematische Medikationsabgleich ist, wie bereits erwähnt, sehr zeit- und ressourcenintensiv (Patiententsicherheit Schweiz, 2017). Ein weiteres Manko ist aus Sicht der Autorinnen ebenfalls, dass der gesamte Medikationsabgleich nur von Ärzten/-innen, Apotheker/-innen und Pharmaassistent/-innen geleitet wird. Die Pflege, ein wichtiger Bestandteil bei der Medikationssicherheit, wird im aufgezeigten Beispiel der Stiftung Patientensicherheit Schweiz nicht erwähnt.

Wie im weiteren Verlauf der Arbeit aufgezeigt wird, konnten keine aktuellen Studien zur Schnittstellenproblematik gefunden werden, die auch die Pflege in ihre Intervention involviert. Zumeist sind es Interventionen geleitet durch Ärzte/-innen oder Apotheker/-innen die hier ansetzen. Das Beispiel der Stiftung Patientensicherheit Schweiz unterstreicht dies zusätzlich.

2.5 5R-Regeln

Im Schweizer Kontext sind die 5R-Regeln der wohl bekannteste Sicherheitscheck durch Pflegefachpersonen. Die 5R-Regeln besagen, dass vor der Verabreichung eines Medikaments die folgenden Punkte überprüft werden sollten (Schmid et al., 2011):

- Richtige/-r Patient/-in
- Richtiges Medikament
- Richtige Dosis
- Richtige Zeit
- Richtige Applikationsart

Zusätzlich wird in der Literatur häufig die richtige Dokumentation als weiterer Kontrollpunkt erwähnt, daher auch die Rede von den 6R-Regeln (Menche, 2014). Jede dieser fünf R-Kontrollfragen steht für eine Käsescheibe im Käsemodell von Reason (Reason,

1995). Erst wenn alle Käsescheiben mit Löchern auf gleicher Höhe stehen, könnten dadurch Fehler entstehen. Da laut der World Heath Organization (2017) die meisten Fehler während der Verabreichung geschehen, sind diese 5R-Regeln unabdingbar für die Patientensicherheit.

2.6 Beers-Kriterien

Ältere Patient/-innen stellen betreffend der Pharmakotherapie ein besonderes Patientenklientel dar. Eine sinkende Nierenfunktion und herabgesetzte Magen-Darm Motilität führt zu Veränderungen in der Pharmakokinetik als auch in der Pharmakodynamik. Zusätzlich leiden ältere Patient/-innen oft an verschiedenen Erkrankungen, die häufig eine Polymedikation zur Folge haben. Durch mehrere verordnete Medikamente, meist von verschiedenen Ärzten, kombiniert mit zusätzlicher Selbstmedikation, wird die Therapie sehr komplex. Dies führt häufig zu Problemen, beispielsweise zu klinisch relevanten Medikamenteninteraktionen (Schwalbe, Freiberg, & Kloft, 2007).

Mark Beers und eine Gruppe von Wissenschaftlern der Universität Georgia (USA) publizierten erstmals im Jahre 1991 die sogenannte «Beers-Liste». Diese Beers-Liste ist ein Instrument zur Optimierung der Medikamententherapie älterer Patient/-innen. Ursprünglich nur für Heimbewohner/-innen gedacht, werden diese Kriterien inzwischen auch allgemein für Verschreibungen im Alter angewendet (Neuner-Jehle, 2011). Da eine der Studien auf der Beers-Liste aufbaut, folgt hier nun eine kurze Erklärung.

Die aktuellste Beers-Liste stammt aus dem Jahr 2003 und besteht aus zwei Teilen (Sinz, 2017). Beim ersten Teil handelt es sich um eine Anordnung von 28 Medikamenten, die prinzipiell bei über 65-Jährigen vermieden werden sollten. Solche Medikamente verstärken in dieser Patientengruppe die unerwünschten Wirkungen oder sind unwirksam. Zum Teil stehen besser verträgliche Alternativen zur Verfügung (Schwalbe et al., 2007; Sinz, 2017). Der zweite Teil der Beers-Liste umfasst 35 Medikamente. Diese Medikamente sollten bei älteren Patient/-innen mit bestimmten Erkrankungen vermieden werden (Schwalbe et al., 2007; Sinz, 2017).

Laut Sinz (2017) gibt es zwei wesentliche Kritikpunkte an den Beers-Kriterien. Die ursprüngliche Liste, ausgelegt auf das amerikanische Gesundheitswesen, weist eine mangelnde Übertragbarkeit auf das Deutsche wie auch das Schweizerische Gesundheitswesen auf. Zudem werden keine therapeutische Alternativen zu den problematischen Medikamenten genannt. Schwabe, Freiberg und Kloft (2007) gingen dieses Problem teilweise bereits im Jahre 2007 an und übersetzten die Beers-Liste ins Deutsche. Zudem wurde die Liste an das deutsche Gesundheitssystem adaptiert.

2.7 Priscus-Liste

Die Priscus-Liste stellt eine Alternative zu den Beers-Kriterien dar, die zugleich mögliche medikamentöse Alternativen zu den problematischen Medikamenten aufzeigt. Die Liste wurde 2010 durch Petra Thürmann, Lehrstuhlinhaberin für Klinische Pharmakologie in Witten (Deutschland), veröffentlicht (Sinz, 2017).

Die Priscus-Liste hilft somit, die oben erwähnten Nachteile der Beers-Liste zu limitieren. Die Priscus-Liste enthält 83 Wirkungsstoffe, die bei älteren Menschen potentiell unangemessen sein können. Sie gibt für fast jeden dieser Wirkungsstoffe mögliche Alternativen an. Falls die Weiterführung der Medikation jedoch nicht vermeidbar ist, werden Empfehlungen für die Praxis, beispielsweise Monitoringparameter und Dosisanpassungen abgegeben (Bundesministerium für Bildung und Forschung, 2018; Sinz, 2017).

2.8 Fazit

Die Theorie zeigt auf, dass die Problematik der Medikationsfehler schon früh erkannt und erste Massnahmen bereits getroffen wurden. Als nächster Schritt steht deren Implementierung und Festigung in die Praxis an. Um aus Fehlern nachhaltig zu lernen und diese in der Zukunft vermeiden zu können, muss ein Wandel der Betrachtung von Fehlern vollzogen werden - vom personenbezogenen Fehler zum Systemfehler.

3 METHODE

Im Folgenden wird das Vorgehen der Autorinnen beschrieben. Dabei wird auf das Design, die Suchstrategie, die Zusammenfassung und Analyse der Literatur wie auch auf die ethischen Aspekte eingegangen.

3.1 Design

Das gewählte Design für diese Bachelorarbeit ist die Literaturübersicht. Diese wird von Mayer (2015) als Synthese von Wissensbeständen beschrieben. Es wird in Büchern, Berichten, Studien wie auch Expertenmeinungen nach Informationen zu einem gewissen Thema gesucht. Welche Quellen und welche Informationen am Ende in die Arbeit aufgenommen werden, ist subjektiv (Behrens & Langer, 2016). Durch die Literaturrecherche wird ein Überblick zu einem bestimmten Thema geschaffen. Sie kann zusätzlich den Themenbereich einschränken. Die Literaturrecherche dient zum Erfassen des aktuellen Stands der Forschung und wird als geeignetes Mittel definiert, um aktuelle und evidenzbasierte Studien zu finden (Mayer, 2015). Für die Beantwortung der Fragestellung wurden in diesem Fall Studien verwendet. Die Anwendbarkeit auf die

Praxis im Schweizer Gesundheitswesen wurde in der Bachelorarbeit zudem kritisch hinterfragt.

3.2 Suchstrategie

3.2.1 Datenbanken und Suchbegriffe

Zur Beantwortung der Fragestellung wurden Forschungsarbeiten in den Datenbanken PubMed und CINAHL gesucht. Die Suchbegriffe wurden vom Deutschen ins Englische übersetzt. Dabei wurde nach Pflege (übersetzt als Nursing), Pflegeinterventionen (übersetzt als Nursing Intervention(s)) und Medikationsfehler (übersetzt als Medication errors) gesucht. Anhand der Hintergrundrecherche wurden die Medikationsfehler erweitert auf Medikamentennebenwirkungen (übersetzt als Drug related side-effects oder adverse drug reaction oder adverse drug events) und unangemessene Medikation (übersetzt als inappropriate medication oder inappropriate prescribing). Es wurde mit Schlagwörtern, Mesh-Terms und Cinahl-Headings gesucht. Die Literaturrecherche wurde zwischen November und Dezember 2017 durchgeführt.

Tabelle 1: Suchbegriffe der Datenbanken

Themenbereiche	PubMed	Cinahl
Medikationsfehler	Medications errors [Mesh] Inappropriate prescribing [Mesh] Drug related side-effects adverse reactions [Mesh]	Medications errors [MH] Adverse drug events [MH] Inappropriate prescribing [MH]
Intervention	Nursing intervention [Schlagwort] Nursing interventions [Schlagwort] Nursing [Mesh]	Nursing interventions [MH]

Die Sucherergebnisse jedes Themenbereiches wurden mit «OR» verknüpft. Anschliessend wurden die zwei Themen (Tabelle 1) mit «AND» verbunden. Schliesslich wurden die Limiten (Tabelle 2) gesetzt. Zusätzliche Studien wurden anhand von Referenzen und Quellen der Fachliteratur gesucht.

Tabelle 2: Suchstrategie

Datenbank	Suchbegriffe (Schlagworte, MESH-Terms oder Cinahl Headings und Textworte) & Operatoren (and, or, not)	Limiten
PubMed	(((“Nursing“[Mesh]) OR (nursing intervention or nursing interventions))) AND (((‘’Medication Errors’’“[Mesh]) OR (‘’Drug-Related Side Effects and Adverse Reactions’’“[Mesh]))) OR ‘’Inappropriate Prescribing‘’ “[Mesh])	Abstract; Published in the last 10 years; Aged: 65+ years
CINAHL	((MH ’’Nursing Interventions’’)) AND ((MH ’’Medication Errors’’) OR (MH ’’Adverse Drug Event’’) OR (MH ’’Inappropriate Prescribing’’))	Published 2007 bis 2017; Aged: 65+ years;

3.2.2 Ein- und Ausschlusskriterien sowie Limiten

Die Interventionen mussten in einem Pflegeheim oder Spital durch die Pflege ausgeführt werden. Die Intervention konnte durch die Pflege geleitet werden, oder auch nur die Partizipation der Pflege beinhalten. Studien aus der Psychiatrie oder anderen spezifischen Abteilungen wie Notfall, Intensivstation oder Pädiatrie wurden ausgeschlossen, ebenso wie Interventionen zu spezifischen Krankheiten.

Folgende Limiten wurden bei der Literaturrecherche gesetzt: «publiziert in den letzten zehn Jahren (2007-2017)» und «Alter: +65». Die Altersgrenze wurde bei 64 Jahren gewählt, da ein Teil der Bevölkerung ab diesem Zeitpunkt in Rente geht und dadurch einen neuen Lebensabschnitt beginnen. Die Zeiteinschränkung auf zehn Jahre wurde gewählt, um möglichst aktuelle Literatur zu finden.

3.3 Zusammenfassung und Analyse der Literatur

Setting, Interventionen, Instrumente, wichtigste Ergebnisse, Schwächen und Stärken wie auch das Evidenzlevel der Studien wurden nach Behrens und Langer (2016) in einer tabellarischen Übersicht zusammengefasst. Die Studien wurden analysiert und kritisch beurteilt nach Behrens und Langer (2016). Die kritische Beurteilung umfasst die Glaubwürdigkeit, die Aussagekraft und die Anwendbarkeit der Studien. Ein Ampelschema wurde erstellt, um die Qualitäten der eingeschlossenen Studien übersichtlich aufzuzeigen. Zu den einzelnen Studien wurde eine tabellarische wie auch eine narrative Synthese erstellt. Nur die relevanten Ergebnisse, passend zu der Fragestellung, wurden berücksichtigt. Anhand der Interventionen wurden die Studien in Kategorien

eingeteilt und innerhalb der Kategorien verglichen. Die Anwendbarkeit der Interventionen im Schweizer Gesundheitswesen wurde in der Diskussion kritisch hinterfragt.

3.4 Ethische Aspekte

Die Forschungsethik basiert auf den Grundprinzipien der Pflegeethik: Autonomie, Gutes tun, nicht Schaden und Gerechtigkeit.

Nach Mayer (2007) ist es das Ziel der Forschungsethik, die Rechte der Menschen, die an den Forschungsstudien teilnehmen, zu schützen. «Ethische Überlegungen bedeuten auch, dass die Forschungsmethoden nach bestem Wissen und Gewissen richtig angewendet werden» (Mayer, 2007). Dies bedeutet, dass die Probanden/-innen in ihrer Integrität respektiert werden müssen. Die Probanden/-innen müssen der Untersuchung oder Intervention freiwillig zustimmen und ihre Anonymität muss gewahrt werden. Ein wichtiger Grundsatz ist zudem, dass aufgrund der Intervention kein psychischer und physischer Schaden hervorgerufen wird (Mayer, 2007).

Bei der kritischen Beurteilung wurde unterhalb der Tabelle ein weiteres Kriterium durch die Autorinnen hinzugefügt. Dabei wurde auf die Zulassung durch eine Ethikkommission geachtet.

4 RESULTATE

In den folgenden Unterkapiteln wird die Auswahl der Studien beschrieben, sowie eine Zusammenfassung der kritischen Beurteilungen mittels Ampelschema präsentiert. Die Ergebnisse der eingeschlossenen Studien wurden anhand ihrer Interventionen in Kategorien gegliedert. Die Ergebnisse wurden innerhalb dieser Kategorien erläutert.

4.1 Auswahl der Studien

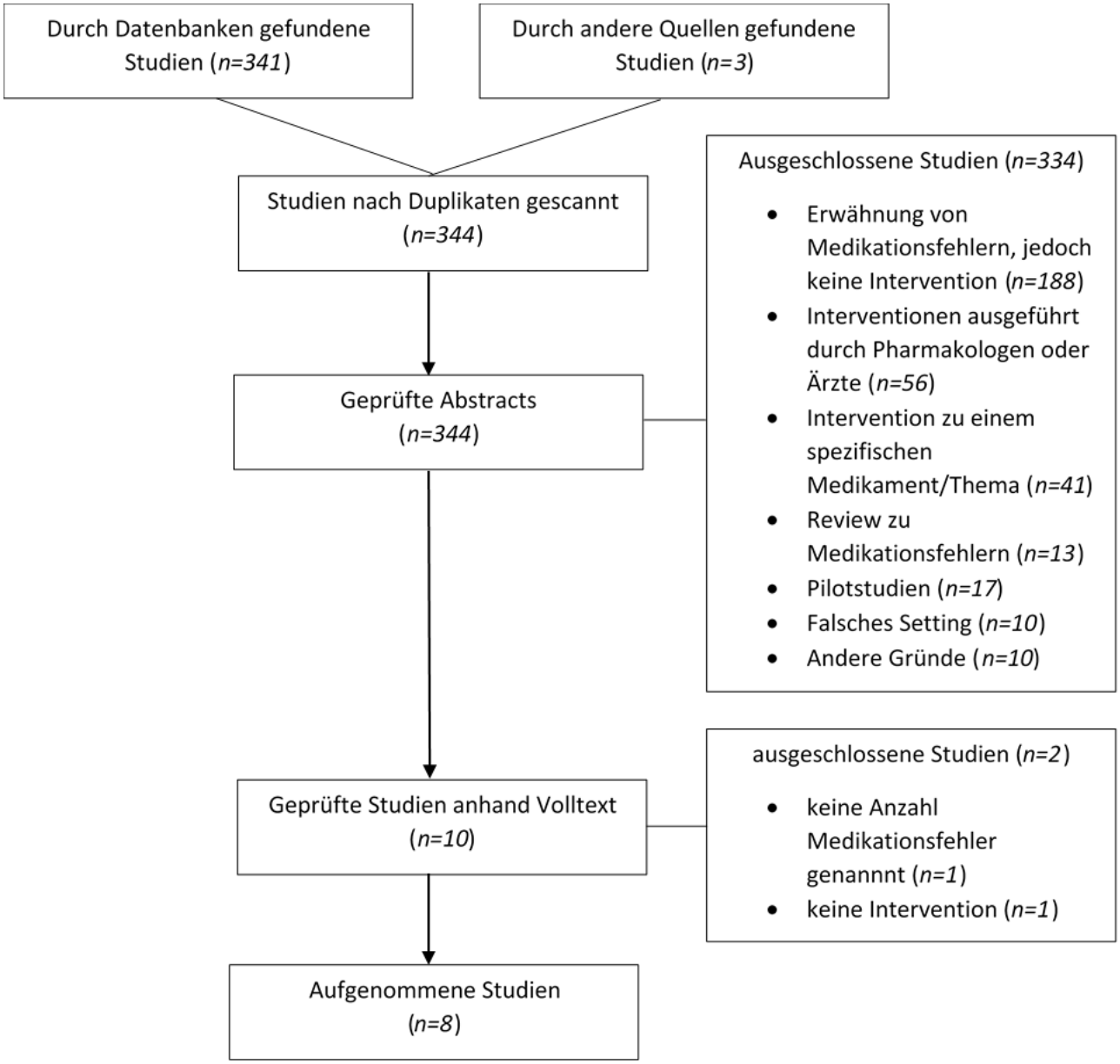

Abbildung 3: Flowchart

4.2 Qualität der eingeschlossenen Studien

Sechs Studien wiesen ein mittleres Evidenzlevel von 2b auf. Eine Studie wies mit 1b ein hohes Evidenzlevel auf, eine weitere mit 3a wiederum ein eher geringeres Evidenzlevel (Behrens & Langer, 2016). Die Qualität der Studien schwankt zwischen sehr gut und mittelmässig. Die Qualitäten der eingeschlossenen Studien wurden anhand eines Ampelschemas (Abbildung 4) dargestellt. Die kritische Beurteilung zeigt anhand ihrer Ergebnisse die Qualität der einzelnen Studien auf. Die Farbe Rot steht für fehlende Informationen, problematische Aspekte oder keine signifikanten Ergebnisse. Unzureichende Informationen, mittlere Qualität oder widersprüchliche Ergebnisse und An-

gaben innerhalb der gleichen Studie wurden mit Gelb gekennzeichnet. Grün steht für stimmige, präzise und ausgeprägte Ergebnisse und Angaben. Alle Felder in weisser Farbe stehen für Fragen die aufgrund des prä-post Designs nicht anwendbar waren.

			Bergqvist et al. 2009	Blozik et al. 2010	Ching et al. 2013	Ching et al. 2014	Henneman et al. 2014	Pitkäjä et al. 2014	Poon et al. 2010	Van Welie et al. 2016
Glaubwürdigkeit	1	Rekrutierung, Randomisierung								
	2	Follow up/Drop outs								
	3	Verblindung								
	4	Basis-Merkmale								
	5	Gleichbehandlung								
	6	Wechsler								
	7	Stichprobengrösse								
	8	Vergleichbarkeit								
Aussagekraft	9	Behandlungseffekt								
	10	Zufälligkeit der Ergebnisse (p-Wert)								
	11	Präzise Ergebnisse (KI)								
Anwendbarkeit	12	Übertragbarkeit								
	13	Alle Aspekte enthalten								
	14	Nutzen/Kosten (NNT)								

Abbildung 4: Ampelschema

4.3 Übersicht der Studien

Bei den acht Studien handelt es sich bei sechs um Prä-Post-Studien, bei einer um eine randomisierte Kontrollstudie und einer weiteren mit einem Mixed-Methods-Design. Die acht Studien wurden in der Schweiz, Schweden, den Vereinigten Staaten von Amerika (USA), Grossbritannien und der Niederlande durchgeführt. Fünf Studien wurden in Spitälern, drei in Pflegeheimen durchgeführt.

Die folgende Tabelle zeigt die wichtigsten Eckpunkte, Daten und Erkenntnisse der eingeschlossenen Studien auf. Die Interventionen wurden in den tabellarischen Übersichten im Anhang genauer beschrieben.

Tabelle 3: Übersicht der eingeschlossenen Studien

Autor (Jahr) ***Land***	**Anzahl TN**	**Intervention und Setting**	**Wichtigsten Ergebnisse**
Bergqvist et al. (2009) ***Schweden***	TN= 460 KG= 210 IG= 250	Schulung «klinische Pharmakologie» und Tools zur Erkennung von unangemessener Medikation Durchführung: Spital in Stockholm	Auftreten von unangemessener Medikation: in KG bei 37 Patient/-innen ein oder mehrere unangemessene Medikamente gefunden, in der IG 43; kein signifikanter Unterschied (p=0.90)
Blozik et al. (2010) ***Schweiz***	TN= 354 KG= 173 IG= 181	Anwendung der Beers-Kriterien (i) Anpassung der Beers-Kriterien an das Schweizer Umfeld; (ii) unangemessene Medikationsidentifikation; (iii) unangemessenes Medikationsabbruchsystem; (iv) Mitarbeiterschulung. Durchführung: Pflegeheim im Kanton Bern	Signifikante Reduktion der unangemessenen Medikamentenverordnung von 14.5% (CI95% 9.2; 19.7) auf 2,8% (CI95% 0.4; 5.3) nach der Intervention
Ching et al. (2013) ***USA***	TN= 2139 KG+IG = 9244 Medikamente	Lean Management Interventionen: (i) Verbesserung des Aussehens / Layout des Medikationsraumes; (ii) Visuelle Kontrolle wie Schild «nicht-Rede-Zone»; (iii) Arbeit standardisieren; (iv) «Do vs. Do not Do» Poster Durchführung: Virginia Mason Medical Center Spital	Signifikante Reduktion (p<0.001) der Medikationsverabreichungsfehler von 10.3 Fehler/100 Medikamente auf 2.8 Fehler/100 Medikamente → entspricht einer absoluten Risikoreduktion RR=7.5 Fehler/100 Medikamente (CI95% 5; 10)
Ching et al. (2014) ***USA***	TN= 3617 KG+IG = 16'149 Medikamente	Barcode Scanning mit Jidoka Prinzipien Durchführung: Virginia Mason Medical Center Spital	Signifikante Reduktion (p<0.001) der Medikationsverabreichungsfehler von 5.9 ±25.5/100 Medikamente auf 3.0 ± 18.2/100 Medikamente → absolute Risikoreduktion 2.9 Fehlern/100 Dosen entspricht (CI 95% 2.2; 3.6)
Henneman et al.	1:TN= 16	Tool zum Medikationsabgleich mit Schulung zur Anwendung des Tools	Phase 1: Verbesserung der Genauigkeit der Medikamentenabstimmung von 74% auf 87% (p=0.01)

(2014) ***USA***	KG= 9 IG= 7 2:TN= 100 KG= 50 IG= 50	Durchführung: Schule für Pflegestudierende (Phase 1), Universitätsspital und Regionalspital (Phase 2)	Phase 2: Senkung der Medikationsfehler betreffend der Medikationsliste um 80% → nicht signifikant (p=0.204) Phase 3: keine Ergebnisse genannt
Pitkälä et al. (2014) ***Finnland***	TN= 227 KG= 109 IG= 118	Schulung für diplomierte Pflegefachpersonen zur schädigenden Medikation Durchführung: Pflegeheime in Helsinki	Signifikante Reduktion (p=0.009) der Häufigkeit schädigender Medikamente nach 12 Monaten um -11.7 Medikamente in IG (CI95% -20.5; -2.9). Keine signifikante Änderung (p=0.022) zwischen IG und KG betreffend der Häufigkeit von vorkommender schädigender Medikamentennutzung
Poon et al. (2010) ***Grossbritannien***	TN= 1'726 KG= 787 IK= 939	Barcode Scanning (elektronische Medikamentenverabreichungssystem (eMAR)) Durchführung: Universitätsspital	Nicht-zeitbedingte Medikamentenabgabefehler: signifikante Reduktion (p<0.001) von 11.5% auf 6.8% Zeitbedingte Medikationsfehler: signifikante Reduktion (p=0.001) von 16.7% auf 12.2%
Van Welie et al. (2016) ***Niederlande***	TN= 314 KG= 164 IK= 150	Schulung zum Mörsern von Medikamenten und Warnsymbole Durchführung: Pflegeheime	Signifikante Reduktion der Anzahl an irrtümlich gemörserten Medikamenten von 21 auf 3 → RR=0.15 (CI95% 0.05; 0.51).

TN= Teilnehmer IG=Interventionsgruppe KG=Kontrollgruppe

4.4 Ergebnisse der Studien

Es konnten vier Kategorien ausgearbeitet werden; Schulungen, Barcode Scanning, Dokumente zum Abgleich und der systemische Ansatz.

4.4.1 Schulungen

Bergqvist et al. (2009) evaluierten, inwiefern eine Schulung zur klinischen Pharmakologie bei Pflegefachpersonen die medikamentöse Therapie bei älteren Patient/-innen verbessern kann. Dabei wurden Informationen zu diesem Thema weitergegeben und Tools vorgestellt, die bei der Identifizierung von medikamentenabhängigen Problemen helfen sollten. Es wurde das Symptom Assessment Form (SYM) vorgestellt. Dieses stellt häufigen Nebenwirkungen der Medikamente vor. Zudem wurde den Pflegenden Zugang zur Janus Web Applikation (JWA), welche bei der Bestimmung von Medikamenteninterkationen hilft, und einer Web-Applikation zur Berechnung der Kreatinin Clearance, der Nierenfunktion, gewährt. Es wurden 460 Patient/-innen bewertet. Davon waren 210 in der Kontrollgruppe (KG) und 250 in der Interventionsgruppe (IG). Beide Gruppen waren in ihren Charakteristika ähnlich. Das Durchschnittsalter lag bei 80.3 Jahren. Das Auftreten von unangemessener Medikation bei Austritt konnte durch die Schulung nicht signifikant (p=0.9) gesenkt werden. In der KG erhielten 37 Patient/-innen ein oder mehrere unangemessene Medikamente, in der IG waren dies 43. Bei 73 der 250 Patient/-innen aus der IG wurde eine Medikamentenüberprüfung gemacht. Ein Wiedereintritt in das Spital konnte durch diese Schulung nicht signifikant reduziert werden (p=0.86). In der IG wurden 94 Patient/-innen nach ihrem Austritt wieder aufgenommen, in der KG lag dieser Wert bei 76. Es gab keine signifikante Differenz zwischen den zwei Gruppen betreffend die medikamentenabhängigen Wiedereintritte in das Spital. 14 Wiedereintritte aus der IG und 16 aus der KG fanden aufgrund von Medikamenten statt. Durch die Tools konnten 86 medikamentenbezogene Probleme bei 53 Patient/-innen entdeckt werden, die ansonsten durch die normale Pflege unerkannt geblieben wären.

Auch Pitkälä et al. (2014) bediente sich einer Schulung, bestehend aus zweimal vier Stunden Training für diplomierte Pflegefachpersonen zum Thema der schädigenden Medikation. Die ersten vier Stunden basierten auf einer Lektüre zu diesem Thema, bei dem die Pflegefachpersonen dazu ermutigt wurden, über ihre Erfahrungen mit medikamentenabhängigen Problemen zu sprechen. Es wurde eine Liste mit schädigenden Medikamenten vorgestellt sowie mögliche Alternativen dazu. In den zweiten vier Stunden wurden Fallstudien genauer betrachtet. Anhand der «problem-based-learning» Prinzipien erörterten die Pflegefachpersonen medikamentenabhängige Probleme. Die

Pflegefachpersonen wurden ermuntert, ihre eigenen Prozeduren und mögliche Verbesserungen zu reflektieren und zu diskutieren. Anschliessend wurde eine Liste der schädigenden Medikamente an alle beteiligten Stationen der Interventionsgruppe ausgehändigt. Die Pflegefachpersonen wurden aufgefordert, diese Liste und ihr Wissen dazu zu gebrauchen, um mögliche medikamentenbedingte Probleme zu identifizieren und den behandelnden Ärzten/-innen mitzuteilen. Dadurch konnte eine mögliche schädigende Medikamentennutzung signifikant (p=0.009) gesenkt werden. Das Sample umfasste hier 227 Bewohner/-innen diverser Pflegeheime in Helsinki (Einschlusskriterien: siehe kritische Beurteilung) mit einem Durchschnittsalter von 83 Jahren. Davon waren 118 Bewohner/-innen in der IG und 109 in der KG. Die Häufigkeit schädigender Medikamente reduzierte sich nach 12 Monaten um -11.7 Medikamente (CI95% -20.5; -2.9) in der IG. In der KG gab es mit +3.4 Medikamente (CI95% -3.7; 10.6) keine signifikanten Veränderungen (p=0.34). Betreffend die Häufigkeit von vorkommender schädigender Medikamentennutzung konnte eine signifikante Veränderung (p=0.022) zwischen IG und KG beobachtet werden. Durch die Intervention konnte in der IG die durchschnittliche Anzahl an Medikamenten zusätzlich signifikant (p=0.0024) um -0.43 (CI95% -0.15; -0.71) verringert werden, blieb in der KG jedoch stabil (p=0.27) mit +0.11 (CI95% -0.09; 3.1). Ein wichtiger Punkt betreffend schädigender Medikamentennutzung ist auch die Anzahl ebendieser. Die Differenz der durchschnittlichen Anzahl an Medikamenten war zwischen IG und KG signifikant (p=0.0035).

Van Welie, Wijma, Beerden, van Doormaal, & Taxis (2016) wollten anhand von positiven und negativen Warnsymbolen auf dem Barcode der Medikamente und einer 20-minütigen Schulung die Häufigkeit von irrtümlich gemörserten Medikamenten in niederländischen Pflegeheimen reduzieren. Durch das automatische Tablettenausgabe- und Verpackungssystem wurden Warnsymbole auf die Verpackungen gedruckt. Es wurden zusätzlich Poster mit der Erklärung der zwei Symbolen auf den Stationen angebracht. Diese sollten als Erinnerungsstütze dienen. Während der Schulung wurden Informationen zu nicht mörserbaren Medikamente gegeben, sowie mögliche Alternativen dazu. Abschliessend wurde den Mitarbeitern ein digitaler Newsletter zugesandt, der den Inhalt der Schulung auf einer Seite zusammenfasste. Van Welie et al. (2016) bewertete hierfür 164 Patient/-innen in der Prä-Gruppe und 150 in der Post-Gruppe. Dies entspricht 681 Medikamentenabgaben in der Prä-Gruppe, bzw. 636 in der Post-Gruppe. Beide Gruppen waren in ihren Charakteristika ähnlich. Das Durchschnittsalter der Teilnehmenden lag bei 81.6 Jahren. Die Anzahl an irrtümlich gemörserten Medikamenten konnte von 21 auf 3 (von 3.1% auf 0.5%) signifikant reduziert werden. Dies entspricht einer relativen Risikoreduktion von RR=0.15 (CI95%, 0.05; 0.51). Die Anzahl an Pati-

ent/-innen mit gemörserten Medikamenten reduzierte sich nicht signifikant (p=0.20) von 19 vor der Intervention auf 11 nach der Intervention (von 11.6% auf 7.3%). Das irrtümliche Mörsern von Medikamenten fand vor der Intervention auf 11 von 18 Stationen (entspricht 61%) statt. Nach der Intervention lag dieser Wert noch bei 3 von 18 Stationen (entspricht 17%).

4.4.2 Barcode Scanning

Ching, Williams, Idemoto, & Blackmore (2014) wollten mit ihrer Studie die Wirksamkeit der Implementierung von Medikamentenverabreichung via Barcode Scanning zusammen mit den Jidoka Prinzipien evaluieren. Historisch gesehen haben sich die Jidoka-Prinzipien auf eine automatische Stoppvorrichtung einer Maschine bezogen, um einen Fehler oder ein fehlerhaftes Produkt zu verhindern, wie z.B. in der Autodindustrie. Jidoka wurde in diesem Fall so angewendet, dass eine Fehlermeldung angezeigt wurde, falls das Medikament nicht mit der verordneten Dosis oder Patient/-innen übereinstimmte. Jidoka hat drei Hauptkomponenten: die Zuordnung von Arbeiten zu Menschen und Maschinen aufgrund ihrer unterschiedlichen Fähigkeiten, Anpassung der Maschinen an den menschlichen Arbeitsablauf und Überwachung der Mensch-Maschine-Interaktion. Spezifisch auf die Studie von Ching et al. (2014) bezogen, bedeutet dies, dass im Vorfeld die Stärken von Mensch und Maschine gegenübergestellt wurden und mit diversen Testversuchen deren bestmöglichste Implementierung in den Pflegeablauf erprobt wurde. Daraus resultierten mehrere Anpassungen. Es wurde festgelegt, welche Codes zu scannen waren und wie mit speziellen Medikamenten zu verfahren sei. Als letztes wurde bei regelmässigen Treffen Probleme betreffend des Barcode Scannings angegangen und verbessert. Für diese Studie wurden 3'617 Patient/-innen mit einem Durchschnittsalter von 64 Jahre (zwischen 18-110 Jahren) bewertet. Dies entspricht 16'149 verteilten Medikamenten. Medikationsfehler reduzierten sich signifikant (p<0.001) von 5.9 ± 25.5/100 Medikamente auf 3.0 ± 18.2/100 Medikamente, was einer absoluten Risikoreduktion von 2.9 Fehlern/100 Dosen entspricht (CI 95% 2.2; 3.6). Nach der Intervention konnte in vier der acht Medikationsverabreichungsfehlern (falsches Medikament, falsche Verabreichungsart, falsche Zeit, Medikament nicht vorhanden) eine signifikante Reduktion (p<0.001) erreicht werden. Die Anzahl der Verstösse gegen die Sicherheitsvorkehrungen konnten signifikant (p<0.001) von 54.8 ± 77.0/100 Medikamentendosen auf 29.0 ± 51.7 Verstösse/100 Medikamentendosen reduziert werden. Dies entspricht einer absoluten Risikoreduktion von 25.8 Fehlern pro 100 Dosen (CI 95% 23.7; 27.9).

Poon et al. (2010) evaluierte den Effekt des elektronischen Medikamentenverabreichungssystems (eMAR) anhand der Medikationsverabreichungsfehler, den möglichen

unerwünschten Medikamentenwirkungen und den Übertragungsfehlern. Anfangs erhielten die Pflegenden eine Schulung à vier Stunden, in der das elektronische Medikamentenverabreichungssystem (eMAR) vorgestellt wurde. Der Medikamentenbarcode und der Barcode des Patientenarmbandes wurden daraufhin vor der Verabreichung des Medikaments gescannt und falls richtig, automatisch dokumentiert. Falls ein Fehler vorlag (z.B. falsche Dosis), wurde eine Warnung abgegeben. Das System warnte die Pflegefachpersonen ebenfalls, wenn eine Medikation überfällig war. Die 1'726 Teilnehmenden der Studie entsprachen 14'041 verabreichten Medikamenten. Das Durchschnittsalter auf den Abteilungen sah folgendermassen aus: Medizinische Abteilung KG: 64.3 ± 17.1; IG 64.6 ± 16.5, Chirurgische Abteilung KG: 58.5 ± 17.0; IG: 58.4 ± 17.8, Intensivstation KG: 62.4 ± 16.7; IG: 61.3 ± 15.3. Es wurden 776 nicht-zeitbedingte Medikamentenabgabefehler auf den Abteilungen ohne eMAR Barcode Scanning (entspricht einer Fehlerrate von 11.5%) und 495 Fehler auf Abteilungen mit eMAR Barcode Scanning (entspricht einer Fehlerrate von 6.8%) beobachtet. Die relativen Risikoreduktion liegt bei RR= -41.4% (CI95% -34.2; -47.6) und ist somit signifikant (p<0.001). Die Anzahl der möglichen unerwünschten Medikamentenwirkungen in Zusammenhang mit den nicht-zeitbedingten Medikamentenabgabefehlern sank signifikant (p<0.001) von 213 (entspricht 3.1%) ohne Verwendung eMAR Barcode Scanning, auf 114 (entspricht 1.6%) durch die Verwendung des Barcode Scanning. Dies entspricht einer relativen Risikoreduktion von RR= -50.8% (CI95% -39.1; -61.7). Die Anzahl der zeitbedingten Medikamentenabgabefehler fiel signifikant (p=0.001) von 1'126 (entspricht 16.7%) auf 891 (entspricht 12.2%) mit dem eMAR Barcode Scanning. Die relative Risikoreduktion liegt hier bei RR= -27.3% (CI95% -21.0; -33.8). Die Anzahl der möglichen unerwünschten Medikamentenwirkungen in Zusammenhang mit den zeitbedingten Medikamentenabgabefehlern verringerte sich nicht signifikant (p=0.44) von 34 (entspricht 0.5%) ohne eMAR Barcode Scanning auf 30 (entspricht 0.4%) mit Barcode Scanning. Dies entspricht einer relativen Risikoreduktion von RR= -18.9% (CI95% -60.4; 25.5).

4.4.3 Dokumente zum Abgleich

Blozik et al. (2010) erzielte mit den adaptierten Beers-Kriterien eine signifikante Reduktion der unangemessenen Medikation. Wie im theoretischen Rahmen bereits erwähnt wurde, handelt es sich bei den Beers-Kriterien um eine Liste mit Medikamenten, die aufgrund diverser Gründe bei älteren Patient/-innen vermieden werden sollten.

Die Intervention umfasste vier Schlüsselelemente. Im Vorfeld wurde eine Anpassung der Beers-Kriterien an das Schweizer Umfeld vorgenommen. Anhand dieser Liste konnten Pflegfachpersonen die unangemessene Medikation identifizieren. Diese wurde

anschliessend gekennzeichnet und eine mündliche Empfehlung zum Stopp des Medikaments an die behandelnden Ärzte/-innen abgegeben. Falls das betroffene Medikament nach zwei Monaten weiterhin verordnet wurde, erinnerten die Pflegefachpersonen die behandelnden Ärzte/-innen nochmals an die Absetzung des Medikaments. Die Studie, die in einem Schweizer Pflegeheim stattfand, involvierte 173 Teilnehmende (Durchschnittsalter: 80.3 ± 8.8 Jahren). Die Anzahl an unangemessenen Medikamentenverordnungen sank von 14.5% (entspricht 25/173) (CI95% 9.2; 19.7) vor der Intervention auf 2,8% (entspricht 5/178) (CI95% 0.4; 5.3) nach der Intervention. Die Bewohner/-innen hatten ein fast fünffach verringertes Risiko einer unangemessenen Medikamentenverordnung nach der Intervention. Die relative Risikoreduktion beträgt RR=0.2 (CI95% 0.06; 0.5). Das Risiko einer unangemessenen Medikamentenverordnung stieg in der Einjahres-Folgeperiode nicht signifikant (RR=1.6; 95% CI 0.5; 6.1) auf 4.4% (CI95% 1.4; 7.4). Das Risiko der unangemessenen Medikamentenverordnung zeigte ein Jahr nach der Intervention einen statistisch signifikanten Rückgang (RR=0.3; CI95% 0.1; 0.7). Nach der Intervention wurde circa ein Drittel aller unangemessenen Medikamente ohne Ersatz gestoppt. Circa die Hälfte der unangemessenen Medikamente wurde durch einen angemessenen Ersatz aus der Beers-Liste ersetzt. Etwa zwei Drittel aller identifizierten unangemessenen Medikamente waren entweder Benzodiazepine oder Antihistaminika. Benzodiazepine und Antihistaminika gehörten auch ein Jahr nach der Intervention immer noch zu den häufigsten verschriebenen unangemessenen Medikamenten.

Henneman et al. (2014) haben den standardisierten Erfassungsbogen zum Medikationsabgleich für die Medikamentengeschichte in drei Phasen evaluiert. Das Tool besteht aus sechs Fragepaketen, welche nacheinander erfragt werden müssen. Es fängt mit den Basisdaten an (demographische Daten, Allergien, Diagnosen, Ärzte). Im Schritt zwei und drei wurden die Medikamente anhand eines vorgegebenen Schemas erfragt. Falls keine genaueren Daten zu den Medikamenten vorhanden waren, wurden diese in Schritt vier weiter vertieft. Als fünfter Schritt wurden die allgemeinen Fakten erfragt. Am Ende wurde eine Übersicht erstellt. In Phase 1 wurde die Genauigkeit der Medikamentenabstimmung durch 16 Pflegestudierende geprüft. Die Genauigkeit verbesserte sich signifikant (p=0.01) über alle Simulationen hin von 74% auf 87%. In zwei der vier Simulationen konnte die Genauigkeit von 73% auf 100%, bzw. von 67% auf 96% verbessert werden. In den anderen Simulationen wurden keine signifikanten Verbesserungen erzielt. Anhand der Rückmeldungen wurde eine verbesserte Version des Tools in Phase 2 angewendet. In der Praxis erhielten die Pflegefachpersonen eine Eins-zu-eins Schulung zur Anwendung des verbesserten Tools. Poster und die Schlüsselkonzepte wur-

den gut sichtbar an den Wänden der Station angebracht. In Phase 2 konnten die Medikationsfehler nicht signifikant (p=0.204) um 80% gesenkt werden. Der prozentuale Anteil der Patient/-innen ohne Unstimmigkeiten wurde signifikant (p=0.017) von 20% auf 42% verbessert. Das Durchschnittalter während dieser Phase lag prä-Intervention bei 68.1 Jahren und post-Intervention bei 69.3 Jahren. Zu Phase 3 wurden keine statistischen Werte angegeben. Das Tool wurde als nützlich, aber sehr zeitintensiv beschrieben.

4.4.4 Systemischer Ansatz

Ching, Long, Williams, & Blackmore (2013) konnten durch das Lean Management die Medikationsverabreichungsfehler signifikant (p<0.001) reduzieren. Um die Problemfelder anzugehen und zu verbessern, wurden die Mitarbeitenden bei ihrer täglichen Arbeit beobachtet. Es wurden time-motion Studien gemacht, um herauszufinden, wie viele Schritte, wie viel Zeit die Pflegefachpersonen in etwa bei der Medikamentenverabreichung brauchen. Zudem wurden Patient/-innen, wie auch Mitarbeiter verschiedener Berufe nach ihren Ideen und Vorschlägen zu verschiedenen Problemfeldern befragt. Anhand all dieser Rückmeldungen und Erkenntnisse wurden Änderungen vorgenommen. Das Layouts des Raumes, indem die Medikamente gerichtet wurden, wurde verbessert. Es wurden visuelle Zeichen angebracht, wie zum Beispiel «nicht-Rede-Zone», eine Leuchte vor dem Medikationsraum, die automatisch einschaltet, falls jemand den Raum betritt oder eine rote Linie am Boden um das Areal zu kennzeichnen. Zusätzlich wurden standardisierte Abläufe implementiert, wie zum Beispiel die weiter unten aufgeführten Sicherheitsvorschriften. «Do vs. Do not Do» Poster, aufgehängt auf allen Abteilungen, erinnerten an die Sicherheitsvorschriften. Durch diese Interventionen konnte eine Senkung der Fehlerrate von 10.3 Fehler/100 Medikamente auf 2.8 Fehler/100 Medikamente beobachtet werden. Dies entspricht einer absoluten Risikoreduktion von RR=7.5 Fehler/100 Medikamente (CI95% 5; 10). Die Verstösse gegen die Sicherheitsvorschriften reduzierten sich signifikant (p<0.001) von 83 Verstösse/100 Medikamente auf 42 Verstösse/100 Medikamente. Die absolute Risikoreduktion entspricht hier 42 Verstösse/100 Medikamente (CI95% 35; 48). Ching et al. (2013) nannten sechs Sicherheitsvorschriften, die befolgt werden mussten: die Medikamente mit der Medikamentenliste vergleichen, die Medikamente von der Zubereitung bis zur Verabreichung etikettiert behalten, zwei Arten der Patientenidentifikation durchführen, die Erklärung des Medikaments an die Patient/-innen, deren sofortige Austragung nach der Verabreichung und den Schutz dieses Prozesses vor Ablenkungen und Unterbrechungen. Die «perfekte Dosis» bestand laut Ching et al. (2013) aus den erfüllten Sicherheitsvorschriften sowie im nicht Vorliegen von Medikationsfehler. Als Medikationsfehler wurden

folgende genannt: nicht autorisiertes Medikament, falsche Dosis, falsche Applikationsform, falsche Verabreichung, falsche Technik, falsche Zeit, zusätzliche nicht verordnete Dosis und Medikament nicht abgegeben, da es nicht erhältlich war. Die Anzahl «perfekte Dosis» konnte signifikant (p<0.001) von 37/100 Medikamente auf 68/100 Medikamente gesteigert werden, was zu einer absoluten Risikoreduktion von 31/100 Medikamente (CI95% 27; 35) führt. Die Untersuchungen fanden in einem Spital mit 13 Abteilungen (=336 Betten) in den Vereinigten Staaten (USA) statt. Das Durchschnittsalter der 2'139 Patient/-innen lag bei 63 Jahren (18-110). Es wurden gesamthaft 9'244 verteilte Medikamente bewertet.

5 DISKUSSION

Im nachfolgenden Kapitel werden die Ergebnisse kritisch hinterfragt. Die Qualität, die Stärken und die Schwächen der einzelnen Studien werden genannt.

5.1 Interpretation der Ergebnisse

5.1.1 Schulungen

Bergqvist et al. (2009), Pitkälä et al. (2014) und auch van Welie et al. (2016) wollten anhand Schulungen Medikationsfehler reduzieren. Nur Pitkälä et al. (2014) und van Welie et al. (2016) konnten signifikante Verbesserungen durch ihre Interventionen erreichen. Daraus lässt sich schliessen, dass der Erfolg der Schulungen vom Inhalt und der Art wie dieser vermittelt wird, abhängig ist. Schulungen zur klinischen Pharmakologie scheinen weniger erfolgreich zu sein, als Schulungen zum Thema der schädigenden Medikation oder des Mörserns der Medikamente. Pitkälä et al. (2014) mit ihrer Schulung und Liste mit schädigenden Medikamenten werden daher empfohlen. Hier muss jedoch eine Anpassung der Liste an die in der Schweiz zugelassenen Medikamente vorgenommen werden. Da die ursprüngliche Liste von den Beers-Kriterien abgeleitet wurde, könnte die Liste von Blozik et al. (2010) dafür verwendet werden. Diese wurde bereits an den Schweizerkontext adaptiert. Die Ergebnisse sind kaum auf einen Zufall zurück zu führen, da das Sample mit 227 Teilnehmenden ausreichend gross gewählt wurde.

Die Intervention von van Welie et al. (2016) wird ebenfalls empfohlen. Dessen Intervention ist jedoch nur durchführbar, wenn bereits ein Barcode Scanner vorhanden ist oder die Verantwortlichen gewillt sind, einen solchen anzuschaffen. Erfolge können nur dann erreicht werden, wenn eine Schulung wie auch ein Scanner gegeben sind. Der Kauf und die Inbetriebnahme eines solchen Scanners wird wiederum zusätzliche Kosten verursachen. Bedenken zum Barcode Scanning werden auf der nächsten Seite ausgeführt. Die Anzahl der Medikamente, die gemörsert wurden, reduzierte sich zwar

signifikant, jedoch nicht die Anzahl Patient/-innen mit gemörserten Medikamenten. Da dennoch eine leichte Reduktion feststellbar war, nehmen die Autorinnen an, dass das Prinzip verstanden wurde, jedoch bei diesen Patient/-innen keine andere Möglichkeit bestanden hatte, die Medikamente zu verabreichen. Die Schulung lässt sich leicht auf das Schweizer Gesundheitswesen adaptieren. Es müsste überprüft werden, ob die jeweiligen Medikamente auch in der Schweiz erhältlich sind. Falls nicht, welche Alternativen hier angeboten werden und ob diese zum Mörsern geeignet sind. Die Überprüfung der Medikamente sowie die Erstellung von möglichen Alternativen müsste jedoch durch einen Pharmakolog/-innen erstellt werden.

Durch Schulungen kann das Bewusstsein für Medikationsfehler gefördert werden. Die Interventionen von Pitkälä et al. (2014) und van Welie et al. (2016) verhindern Fehler bei der Vorbereitung und Anwendung der Medikamente. Pitkälä et al. (2014) nehmen zusätzlich auch die Medikationsanalyse und das Monitoring in ihrer Intervention auf. Dadurch können nicht wirksame oder schädliche Medikamente weggelassen werden. Dies ist aufgrund des veränderten Metabolismus bei älteren Personen besonders wichtig. Dadurch, dass bei beiden Interventionen die einzelnen Medikamente nochmals genauer betrachtet werden, entsteht eine weitere Sicherheitsbarriere nach Reason (1995). Durch diesen weiteren Kontrollpunkt im interdisziplinären Ablauf steigt die Chance, dass Medikationsfehler entdeckt werden und unerwünschte Ereignisse verhindert werden können.

Da Bergqvist et al. (2009) keine signifikanten Verbesserungen vorzeigen konnten, ist diese Intervention nicht zu empfehlen. Die Intervention zielte darauf, Fehler bei der Medikationsanalyse und beim Monitoring zu verhindern. Die Tools dieser Schulung sind in den Augen der Autorinnen angebracht und verständlich. Nur bei 73 der 250 Patient/-innen aus der IG wurde eine Medikamentenüberprüfung gemacht. Wäre diese Medikamentenüberprüfung bei allen Patient/-innen konsequent angewendet worden, so hätte vielleicht eine signifikante Verbesserung erreicht werden können. Warum diese nicht konsequent angewendet wurde, darüber kann nur spekuliert werden. Fehlende Motivation oder Zeit seitens des Personals oder womöglich auch fehlende Kompetenzen könnten der Grund hierfür gewesen sein.

Da die Interventionen zur Schulung in unterschiedlichen Settings stattfanden, kann keine allgemeine Bedeutung für ein Setting abgeleitet werden.

5.1.2 Barcode Scanning

Poon et al. (2010) wie auch Ching et al. (2014) konnten mit dem elektronischen Barcode Scanning signifikante Resultate erzielen. Ihre Vorgehensweise unterschied sich

in der Implementierung des Barcode Scanners. Während sich Ching et al. (2014) bemühte, durch diverse Tests und Nachforschungen das Barcode Scanning an die Gegebenheiten anzupassen und zu verbessern, führten Poon et al. (2010) das Barcode Scanning ohne vorherige Anpassungen ein. Es konnte bei beiden die gleichen statistisch signifikanten Unterschiede (Poon et al. $p<0.001$, Ching et. al. $p<0.001$) erreicht werden. Das Barcode Scanning scheint daher eine effektive Methode zur Reduzierung der Medikationsfehler zu sein. Beide, Ching et al. (2014) wie auch Poon et al. (2010), könnten mit ihren Interventionen in der Praxis erfolgreich sein. Die Anschaffung eines Barcode Scanners ist jedoch mit Kosten verbunden. Die Amortisierung dieser Kosten wurde in keiner der Studien genannt. Eine Studie aus der USA zeigt auf, dass pro Barcode-fähigem Patientenbett in den ersten fünf Jahren 40'000 US-Dollars veranschlagt werden müssen. Diese Kosten beruhen auf der Implementierung und Betrieb eines Barcode Scanning Systems wie auch eines angepassten elektronischen Apothekenmanagements und der Neuverpackung von Medikamenten. Hochgerechnet auf eine 100-Betten Institution sind dies zwischen 3.5 und 5.5 Millionen in den ersten fünf Jahren (Sakowski & Ketchel, 2013). Dies ist ein Betrag, den sich nicht alle Institutionen leisten können. Kleinere Spitäler oder Pflegeheime könnten dadurch abgeschreckt werden. Arbeitgeber werden aufgrund der finanziellen Minderkosten die Implementierungsweise von Poon et al. (2010) der von Ching et al. (2014) vorziehen. Möchten Arbeitgeber jedoch auf langfristige Zeit Erfolg haben, so scheint der Ansatz von Ching et al. (2014) der bessere Weg zu sein. Aufgrund der Einbeziehung der Mitarbeitenden bei der Implementierung und Anpassung wird speziell auf die Bedürfnisse der Angestellten eingegangen. Systemische Faktoren wie auch Umgebungsfaktoren werden miteinbezogen und sorgen für ein sicheres Arbeitsumfeld. Dies unterstützt wiederum die Theorie von Reason (1995). Durch mehrere Sicherheitschecks des zu verabreichenden Medikaments an den Patienten/-in kann eine mögliche Anreihung von Sicherheitslücken (Käselöcher bei Reason) so gering wie möglich gehalten werden. Dabei orientiert sich der Ablauf des elektronischen Barcode Scannings an den 5R-Regeln.

Durch das Barcode Scanning können Fehler bei der Vorbereitung, bei der Abgabe, der Anwendung sowie bei der Dokumentation verhindert werden. Dadurch, dass jede Medikamentenpackung gescannt wird, werden Fehler bereits bei der Vorbereitung erkannt. Eine weitere Sicherheitsbarriere ist die Abgabe. Dabei muss der Barcode der/-s Patient/-innen gescannt werden und das zu verabreichende Medikament mit der elektronischen Verordnung übereinstimmen. Die richtige Anwendung wird durch das Barcode Scanning unterstützt, indem an die richtige Dosis und Einnahmezeit erinnert wird. Die Dokumentation wird bei korrekter Abgabe automatisch erledigt.

Die Autorinnen haben recherchiert, ob das Barcode Scanning für Medikamente bereits in der Schweiz angewendet wird. Bis zum Zeitpunkt der Beendigung dieser Bachelorarbeit war den Autorinnen kein Spital oder Pflegeheim bekannt, in denen das Barcode Scanning für die Abgabe aller Medikamente genutzt wurde. Der Austausch mit einer Pflegenden hat jedoch gezeigt, dass im Inselspital Bern bei der Gabe von Zytostatikatherapien der Barcode des Medikaments gescannt wird. Eigene Erfahrungen der Autorinnen während der Praktika haben gezeigt, dass bereits heute Barcode Scanner in Spitälern in Betrieb sind. Diese werden jedoch nicht für das Medikamentenscanning genützt, sondern vermehrt zur Einteilung oder Kategorisierung von Patientendaten. Der Grundbaustein für das Barcode Scanning von Medikamenten wäre dementsprechend bereits vorhanden. Ching et al. (2014), Poon et al. (2010) und auch van Welie et al. (2016) haben die Anwendung des Gerätes beschrieben, jedoch nicht wie die personelle Situation oder die Einbettung in den Pflegealltag aussieht. Wird damit gerechnet, dass jede Pflegefachperson einen Scanner hat und für die Medikamentenverteilung an ihre Patient/-innen zuständig ist? Oder gäbe es einen Scanner und nur eine zuständige Person, die für die Medikamentenverteilung der Ganzen Abteilung verantwortlich ist? Hier ist noch vieles unklar. Dies kann aber auch zum Vorteil der Spitäler und Pflegeheime sein. Diese könnten sich für eine Variante entscheiden, die an ihre finanziellen Ressourcen, wie auch institutionellen Abläufe oder Teambesetzungen adaptiert ist.

Die Interventionen von Ching et al. (2014) und Poon et al. (2010) wurden beide im Spitalsetting erfolgreich getestet. Die Autorinnen sind der Meinung, dass deren Übertragung in das Langzeitsetting der Pflegeheime auch möglich ist. Van Welie et al. (2016) mit seiner Intervention ist der Beweis dafür, dass dies bereits so angewendet wird.

5.1.3 Dokumente zum Abgleich

Standardisierte Fragebögen oder Listen zum Abgleich nutzten Blozik et al. (2010) und Henneman et al. (2014). Mit diesen Interventionen konnten sie teils signifikante Ergebnisse erreichen. Die Beers-Kriterien sind signifikant effektiv in der Reduzierung von Medikationsfehlern. Die Anwendung der Beers-Kriterien nach Blozik et al. (2010) sind daher sehr zu empfehlen. Nicht nur aufgrund der Ergebnisse, sondern auch weil deren Implementierung bereits an den Schweizer Kontext angepasst ist. Zudem wurde diese Liste stetig an den Wandel der Pharmazie angepasst und erneuert (siehe Kapitel 2.6). Obwohl das Risiko einer unangemessenen Medikamentenverordnung in der Einjahres-Folgeperiode nicht signifikant anstieg, könnte daraus interpretiert werden, dass das Wissen oder die Achtsamkeit nachgelassen hat. Als Gegenmassnahme würden die Autorinnen ein Refresher zu den Beers-Kriterien nach einem Jahr vorschlagen. Durch die Intervention, wie sie durch Blozik et al. (2010) beschrieben wird, können Fehler bei

der Vorbereitung vermieden werden. Würden die Beers-Kriterien bereits durch die Ärzte/-innen angewendet werden, so würden Fehler bei der Verordnung verhindert werden. Durch die Medikationsanalyse und das Monitoring durch eine Pflegefachperson wird eine weitere Sicherheitsbarriere eingebaut. So hätte man laut Reason (1995) mehrere Personen, die im System für eine erfolgreiche Abwehr von Fehlern verantwortlich wären. Der Fokus würde dadurch nicht auf der menschlichen, sondern auf der systemischen Komponente liegen.

Das Tool von Henneman et al. (2014) konnte zwar in der Simulationsphase signifikante Verbesserungen erreichen, in der Praxis hingegen konnten die Medikationsfehler betreffend die Genauigkeit der Medikationsliste nicht signifikant gesenkt werden. Dies obwohl die Medikationsfehler betreffend die Medikationsliste um 80% gesenkt werden konnte. Mit einer grösseren Anzahl an Probanden hätten die Ergebnisse eventuell zu Gunsten der Intervention ausfallen können. In Phase drei wurde das Tool als sehr zeitintensiv beschrieben. Darin sehen die Autorinnen einen weiteren möglichen Grund weshalb in Phase zwei, der Praxis, keine signifikanten Ergebnisse erreicht wurden. Durch diese Intervention könnten Fehler bei der Informationsbeschaffung minimiert werden. Das Tool erinnert an den systematischen Medikationsabgleich von Progress! «sichere Medikation». Auch beim Pilotprojekt «sichere Medikation» gaben die Befragten Institutionen an, dass es zeit- wie auch ressourcenintensiv sei und es daher nicht weitergeführt werde. Dies legt den Verdacht nahe, dass das Tool aufgrund mangelnder Zeit wohl nicht korrekt angewendet wurde oder weggelassen wurde und dadurch möglichen Diskrepanzen nicht erkannt wurden. Eine Anpassung des Tools an den realen Pflegealltag (Zeit und personelle Ressourcen), könnte die Beliebtheit und Effizienz des Tools steigern.

Da beide Interventionen, Blozik et al. (2010) und Henneman et al. (2014), in unterschiedlichen Settings getestet wurden, kann kein direkter Vergleich hergestellt werden. Da die Beers-Kriterien heutzutage in allen Setting angewendet werden, lässt sich eine Übertragung in das Spitalsetting ohne weiteres durchführen (Neuner-Jehle, 2011). Dabei müsste jedoch evaluiert werden, ob die Zeit seitens der Pflege für diese zusätzliche Tätigkeit reicht. Besonders im schnelllebigen Spitalalltag könnte dies ein Hindernis darstellen.

5.1.4 Systemischer Ansatz

Ching et al. (2013) konnten mit ihrer Studie zum Lean Management aufzeigen, dass systemische Faktoren sehr wohl eine signifikante Rolle im Medikationsprozess spielen. Aufgrund von Erneuerungen und Umbauten des Systems konnten die Medikationsfeh-

ler signifikant reduziert werden. Dies bestätigt aber mit seinen Resultaten den systemischen Ansatz von Reason (1995). Daher kann dieser Ansatz zur Reduktion von Medikationsfehlern empfohlen werden. Die Anpassungen, die in der Studie vorgenommen wurden, können jedoch nicht so übernommen werden. Das Lean Management funktioniert in diesem Falle nur, wenn die Veränderungen an die jeweiligen Bedürfnissen der Mitarbeitenden der Institution angepasst werden. Somit wäre dies auch im Schweizer Gesundheitswesen anwendbar. Wie viele der möglichen Veränderungen vorgenommen werden, ist vom finanziellen Budget, den baulichen Möglichkeiten, dem Wille, aber auch von rechtlichen Fragen abhängig. Daher ist es unabdingbar, dass die Leitung der jeweiligen Institution diese Veränderungen unterstützt. Aufgrund der hohen finanziellen Kosten des Ganzen werden wohl eher grössere Heime und Spitäler mit grösseren finanziellen Rücklagen von dieser Intervention profitieren. Die Sicherheitsvorschriften, die Ching et al. (2013) als Teil ihrer Interventionen integriert hatten, zeigen Teile der 5R-Regeln auf. Werden diese 5R-Regeln also wirklich regelmässig in der Praxis angewendet, so könnten Medikationsfehler verringert werden. Dadurch können Fehler in den Bereichen der Abgabe, der Vorbereitung und der Anwendung reduziert werden.

5.2 Stärken und Schwächen der eingeschlossenen Studien

Bei Pitkälä et al. (2014) handelt es sich um eine randomisierte Kontrollstudie und zeigt dadurch eine hohe Evidenz auf. Somit konnten direkte Vergleiche zwischen der Interventions- und Kontrollgruppe gemacht werden. Die Studie von Henneman et al. (2014) beinhaltete ein prä-post Design mit einem deskriptiven Anteil. Die Evidenz liegt hier im unteren Bereich. Die restlichen Studien wurden im prä-post Design durchgeführt und zeigen eine mittlere Evidenz auf (Bergqvist et al., 2009; Blozik et al., 2010; Ching et al., 2013, 2014; Poon et al., 2010; van Welie et al., 2016). Dies hat zur Folge, dass es in diesen Studien keine Kontrollgruppe gibt, sondern jeweils prä- und post-Interventionsgruppen. Die Autorinnen sehen dies nicht als Schwäche an, sondern als einen wichtigen Punkt, der bei der Beurteilung der Studien beachtet werden muss.

Die Studien wiesen im Allgemeinen eine mittlere Glaubwürdigkeit auf. Die Rekrutierung und die Randomisierung wurde bei Bergqvist et al. (2009) und Pitkälä et al. (2014) vollständig beschrieben und gilt als Stärke. In vier der acht Studien wurden die Rekrutierung und die Randomisierung nur teilweise erwähnt (Blozik et al., 2010; Ching et al., 2013; Ching et al., 2014; Poon et al., 2010). Die fehlende Rekrutierung und Randomisierung bei Henneman et al. (2014) und van Welie et al. (2016) wird als Schwäche gesehen. Aufgrund der fehlenden KG war das Kriterium Flow-up und Drop-out war in allen Prä-Post-Studien nicht anwendbar. Die Nennung des Follow-up und Drop-out wird bei Pitkälä et al. (2014) hingegen als Stärke verbucht.

Die Verblindung und die Gleichbehandlung können lediglich bei Pitkälä et al. (2014) als Stärke genannt werden. Bei den restlichen sieben Studien war aufgrund des prä-post Designs keine Gleichbehandlung möglich. Auch die Verblindung wurde nur teilweise oder gar nicht eingehalten (Bergqvist et al., 2009; Blozik et al., 2010; Ching et al., 2013; Ching et al., 2014; Henneman et al., 2014; Poon et al., 2010; van Welie et al., 2016).

Die Einhaltung der Basismerkmale kann bei fünf der acht Studien als Stärke genannt werden (Bergqvist et al., 2009; Blozik et al., 2010; Henneman et al., 2014; Poon et al., 2010; van Welie et al., 2016).

Positiv ist die Powerberechnung und -einhaltung bei Bergqvist et al. (2009), Ching et al. (2014), Pitkälä et al. (2014) und van Welie et al. (2016). Bei Bergqvist et al. (2009) wurde beschrieben, dass die Power eingehalten wurde. Um jedoch die Rate der Wiedereintritte in das Spital statistisch zu prüfen, war das Sample wiederum zu klein. Ching et al. (2013) beeindruckte mit einer grossen Stichprobe (*n*=9'244 verteilte Medikamente). Das Fehlen einer Powerberechnung wird hier jedoch trotzdem als Kritikpunkt angebracht. Bei Blozik et al. (2010), Henneman et al. (2014) und Poon et al. (2010) wurde keine Powerberechnung genannt und gilt somit als Schwäche.

Die Aussagekraft war im Allgemeinen sehr hoch und wird als Stärke angerechnet. Bei allen Studien ist man in der Literatur auf vergleichbare Resultate gestossen. Alle, ausser Bergqvist et al. (2009) und Henneman et al. (2014), konnten eine Signifikanz, einen Behandlungseffekt wie auch die Präzision der Ergebnisse erreichen.

Die Anwendbarkeit der eingeschlossenen Studien wurde anhand der Übertragbarkeit und des Kosten-Nutzen-Verhältnis kritisch beurteilt. Die Übertragbarkeit bezieht sich hauptsächlich auf die Population und die Kultur der Probanden. Da bei Bergqvist et al. (2009) der Nutzen der Intervention nicht signifikant war, unterlag der mögliche Nutzen den möglichen Kosten. Dies muss als Schwäche angesehen werden. Blozik et al. (2010), Ching et al. (2013), Ching et al. (2014), Pitkälä et al. (2014), Poon et al. (2010) und van Welie et al. (2016) zeigen ein gutes Kosten-Nutzen-Verhältnis auf und ist somit eine Stärke der Studien. Bei allen Interventionen mit einem Barcode Scanner muss jedoch bei der Anschaffung eines solchen Geräts mit etwas höheren Anfangskosten gerechnet werden. Bei allen Interventionen ist zu nennen, dass deren Testung jeweils in einem Spital oder Pflegeheim stattgefunden hat, nie in beiden Settings. Dementsprechend ist die Übertragbarkeit nicht gewährleistet. Das Alter der Probanden aus zwei Studien stimmte nicht mit dem Alter in der Fragestellung überein (Ching et al.,

2013; Poon et al., 2010). Somit ist deren Übertragung auf die Population nicht gewährleistet.

Die Studien wurden auf ihre ethischen Aspekte hin geprüft. Die Zulassung durch eine Ethikkommission wurde bei Blozik et al. (2010) und Bergqvist et al. (2009) genannt. Bei Pitkälä et al. (2014) war die Zulassung durch die Ethikkommission und die schriftlichen Teilnahmebestätigungen der Probanden, bzw. deren gesetzlicher Vertreter vorhanden. Diese genannten Punkte werden als positiv bewertet. Als Schwäche muss die fehlende Ethikzulassung bei Henneman et al. (2014) und van Welie et al. (2016) erwähnt werden. Die Studien von Ching et al. (2013) und Ching et al. (2014) wurde von der Ethikkommission als Qualitätsverbesserungsintervention angesehen und daher von einer förmlichen Prüfung ausgenommen.

5.3 Stärken und Schwächen der vorliegenden Arbeit

Als Stärke der Arbeit sehen die Autorinnen die Aktualität der Studien. Die älteste Studie ist aus dem Jahre 2009 (Bergqvist et al., 2009). Dies zeigt zugleich auch die Aktualität der Thematik auf.

Das Evidenzlevel der eingeschlossenen Studien war sehr unterschiedlich. Bei einer Studie handelte es sich um eine randomisierte Kontrollstudie mit einem sehr hohes Evidenzlevel (Pitkälä et al., 2014). Ein sehr geringes Evidenzlevel zeigte hingegen die Studie von Henneman et al. (2014), die Mixed-Methods-Design beinhaltete, auf. Die restlichen Studien wurden mit einem mittleren Evidenzlevel ausgewiesen (Bergqvist et al., 2009; Blozik et al., 2010; Ching et al., 2013, 2014; Poon et al., 2010; van Welie et al., 2016). Bei diesen Studien handelte es sich um Prä-Post-Studien. Die Ergebnisse sind deshalb nicht mit randomisierten Studien vergleichbar. Die Ergebnisse und deren Vergleiche müssen daher mit Vorsicht interpretiert werden.

Als Manko dieser Arbeit muss das kombinierte Setting erwähnt werden. Alle Studien wurden entweder in einem Pflegeheim oder in einem Spital durchgeführt. Dies erschwert die Vergleichbarkeit der Studien. Da die Interventionen jedoch auf das Pflegepersonal ausgerichtet waren, sollten die Anwendungen auch in anderen Settings durchführbar sein. Eine Studie mit der gleichen Intervention in beiden Settings hätte Aufschluss geben können, inwiefern die Intervention adaptierbar wäre.

Als weitere Schwäche der Arbeit können die Studien von Ching et al. aus dem Jahre 2013 wie auch 2014 genannt werden. Deren Intervention wurde nicht spezifisch auf die ältere Population ausgelegt. Die Studie beinhalt auch Daten von jüngeren Patient/-innen (ab dem 18. Lebensjahr). Das Durchschnittalter der Studie aus dem Jahr 2013 liegt mit 63 Jahren leicht unter dem vorgegebenen Alter. Das Durchschnittsalter aus

der Studie aus dem Jahr 2014 stimmt mit dem aus der Fragestellung überein. Die Autorinnen schlossen die Studien dennoch mit ein, da sie den systemischen Ansatz beleuchten und laut der Meinung der Autorinnen auch im Kontext bei älteren Menschen anwendbar sind. Die Autorinnen sind sich dieser Schwäche ihrer Arbeit bewusst und interpretierten die Ergebnisse mit Vorsicht. Dies ist keine Schwäche der eigentlichen Studie, sondern wirkt sich vielmehr auf die Beantwortung der Fragegestellung aus.

Auch die Studie von Poon et al. (2010) muss als möglicher Schwachpunkt aufgeführt werden. Die Studie wurde auf drei Abteilungen durchgeführt – Medizin, Chirurgie und Intensivstation. Als Ausschlusskriterium der Autorinnen wurde anfangs die Durchführung auf spezifischen Abteilungen genannt. Da die Studie nicht ausschliesslich auf der Intensivabteilung durchgeführt wurde, wurde der Artikel trotzdem bewusst eingeschlossen. Als weiteres Manko muss der Altersdurchschnitt genauer erwähnt werden. Der Altersdurchschnitt auf der Medizinabteilung entspricht dem der Fragestellung. Der Durchschnitt auf der Intensivabteilung liegt bei 61.3 ± 15.3 (Abteilungen mit Barcode) und bei 62.4 ± 16.7 (Abteilungen ohne Barcode). Auf der Chirurgie liegt der Wert bei 58.5 ± 17.0 auf Abteilungen ohne Barcode, und mit Barcode bei 58.4 ± 17.8. Dieser Artikel wurde trotzdem bewusst miteinbezogen, da bei der Vorbereitung und Abgabe der Medikamente die Pflegenden die Hauptaufgabe haben. Das Alter der Patient/-innen spielt daher in diesem Fall kaum eine Rolle. Auch sind die Autorinnen der Meinung, dass der Barcode Scanner unabhängig des Patientenalters eingesetzt werden kann.

Dadurch, dass viele Studien wie auch die Fachliteratur in Englisch waren, können Übersetzungsfehler, trotz guter Englischkenntnisse der Autorinnen, nicht ausgeschlossen werden.

Als einer der schwierigsten Punkte empfanden die Autorinnen die Literaturrecherche. Dies weil es anfangs einige Rückschläge zu überwinden gab, die die Motivation zusätzlich hemmten. Die relativ geringe Erfahrung mit Literaturübersichten wirkte hier zusätzlich noch erschwerend. Durch stetiges, organsiertes Arbeiten konnte jedoch gut aufgeholt werden und die Motivation wieder hergestellt werden. Ein kritischer Punkt waren jeweils auch die Beurteilungen der Studien, auf denen diese Arbeit aufgebaut ist. Im Verlaufe der Arbeit wurden teilweise Fehler in den Übersichten und Beurteilungen entdeckt und korrigiert. Dies hatte auch Auswirkungen auf die restliche Arbeit, die dementsprechend überarbeitet werden musste.

6 SCHLUSSFOLGERUNGEN

In diesem Kapitel wird geprüft, inwiefern die Fragestellung «Welche Interventionen können zur Reduktion von Medikationsfehlern in der Pflege von Patient/-innen ab dem 64. Lebensjahr im Spital und Pflegeheim beitragen?» beantwortet werden konnte. Es werden zudem Empfehlungen für die weitere Forschung abgegeben.

6.1 Beantwortung der Fragestellung

Es gibt Interventionen zur Reduzierung von Medikationsfehler die generationenübergreifend, aber auch solche, die spezifisch auf ältere Patient/-innen ausgerichtet sind. Generationenübergreifend zeigte der systemische Ansatz von Ching et al. (2013) signifikante Verbesserungen(Ching et al., 2013). Auch technische Hilfsmittel wie Barcode Scanner können bei jüngeren wie auch älteren Patient/-innen angewendet werden (Ching et al., 2014; Poon et al., 2010). Auch diese zeigten signifikante Verbesserungen hinsichtlich der Medikationsfehler. Jedoch entsprach das Durchschnittsalter bei Ching et al. (2013) und Poon et al. (2010) nicht dem der Fragestellung. Deren Ergebnisse können dementsprechend nicht ohne Zweifel auf die besagte Altersgruppe angewendet werden.

Zusätzlich können Schulungen zur Reduzierung von Medikationsfehlern beitragen. Der Erfolg ist dabei vom Inhalt abhängig. Schulungen zum Thema der schädigenden Medikation (Pitkälä et al., 2014) und zum Mörsern von Medikamenten (van Welie et al., 2016) zeigten signifikante Verbesserungen und sind daher den Schulungen zur klinischen Pharmakologie vorzuziehen (Bergqvist et al., 2009), welche keine signifikanten Veränderungen aufweisen konnten.

Dokumente zur Aufnahme der Medikamentengeschichte erbrachten keinen nachgewiesenen Erfolg (Henneman et al., 2014). Dokumente zum Abgleich von unangemessener Ist- und Soll-Medikation anhand der Beers-Kriterien sind hingegen erfolgreich und werden der Praxis empfohlen (Blozik et al., 2010). Bei Blozik et al. (2010) sollte nochmals auf die bereits geprüfte Durchführbarkeit im Schweizer Gesundheitswesen hingewiesen werden. Alle anderen Interventionen können mit einigen Anpassungen auch im Schweizer Gesundheitswesen umgesetzt werden. Die genauen Änderungen für die Implementierung ins hiesige Gesundheitssystem wurden bereits im Kapitel «5.1 Interpretation der Ergebnisse» diskutiert.

6.2 Empfehlungen für weitere Forschung

Es wurden deutlich mehr Studien zum Vorkommen von Medikationsfehler gefunden als zu Interventionsstudien. Dabei hat sich herausgestellt, dass viele Interventionen für Pharmakologe/-innen und Ärzte/-innen, jedoch wenige für Pflegefachpersonen, vor-

handen sind. Besonders dünn gesät sind Interventionen in Pflegeheimen, wie auch Interventionen, die die Transition von einem Setting zu einem anderen betreffen. Hier wird weitere Forschung benötigt, zumal ein Grossteil der älteren Bevölkerung mehrere Medikamente zu sich nimmt und sich deren Anzahl und Zusammensetzung stetig, je nach Gesundheitszustand, ändert. Oftmals werden bei einem Übergang von einem zum anderen Setting die Medikationslisten geändert. Die inkorrekte Einnahme der Medikamente kann daraufhin zu medikamentenbedingten Problemen führen und der Gesundheit schaden. Deshalb sollten in diesen Themenbereichen vermehrt Forschung betrieben werden.

Die Autorinnen empfehlen, dass zukünftige Interventionsstudien für die Pflege als randomisierte Kontrollstudien durchzuführen sind. Damit wird ein höheres Evidenzlevel erreicht. Dies wird selbstverständlich nicht immer anwendbar sein, sollte jedoch bei Studien, die in grösseren Institutionen durchgeführt werden, in Betracht gezogen werden. Zudem sollten vermehrt Interventionen im selben Setting stattfinden, aber in verschiedenen Institutionen. Dadurch wird eine höhere Vergleichbarkeit und Anwendbarkeit innerhalb desselben Settings erlangt. Es lassen sich spezifische Rückschlüsse auf eine Zielgruppe ziehen.

Wenn die oben genannten Empfehlungen sowie die Interventionen mit signifikanten Ergebnissen von Kapitel «6.1 Beantwortung der Fragestellung» angewendet, ausgebaut und immer wieder auf ihre Erfolge hin kritisch beurteilt werden, so ist davon auszugehen, dass die Fehlerrate sinkt und weniger Patient/-innen von einem unerwünschten Ereignis betroffen sind. Je weniger davon betroffen sind, desto geringer werden auch die Gesundheitskosten. Eintritte in das Spital aufgrund Medikationsfehler könnten dadurch reduziert bis gar vermieden werden.

7 LITERATURVERZEICHNIS

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ANHANG A: SELBSTÄNDIGKEITSERKLÄRUNG

Wir erklären hiermit, dass wir diese Arbeit selbständig verfasst haben. Alle Stellen, die wörtlich oder sinngemäss aus Quellen übernommen wurden, haben wir als solche kenntlich gemacht.

Ort, Datum, Unterschrift

Ort, Datum, Unterschrift

ANHANG B: SUCHPROTOKOLL

CINAHL:

Search ID#	Search Terms	Search Options	Actions
S7	((MH "Nursing Interventions")) AND (S1 OR S2 OR S3)	**Limiters** - Published Date: 20070101-20171231 **Narrow by SubjectAge:** - aged: 65+ years **Search modes** - Find all my search terms	View Results (10) | View Details | Edit
S6	((MH "Nursing Interventions")) AND (S1 OR S2 OR S3)	**Limiters** - Published Date: 20070101-20171231 **Search modes** - Find all my search terms	View Results (32) | View Details | Edit
S5	((MH "Nursing Interventions")) AND (S1 OR S2 OR S3)	**Search modes** - Find all my search terms	View Results (37) | View Details | Edit
S4	(MH "Nursing Interventions")	**Search modes** - Find all my search terms	View Results (7,076) | View Details | Edit
S3	(MH "Inappropriate Prescribing")	**Search modes** - Find all my search terms	View Results (1,540) | View Details | Edit
S2	(MH "Adverse Drug Event")	**Search modes** - Find all my search terms	View Results (9,221) | View Details | Edit
S1	(MH "Medication Errors")	**Search modes** - Find all my search terms	View Results (11,989) | View Details | Edit

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History

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Search	Add to builder	Query	Items found	Time
#18	Add	Search (((**"Nursing"[Mesh]) OR (nursing intervention or nursing interventions))) AND (((**"Medication Errors"[Mesh]) OR ("Drug-Related Side Effects and Adverse Reactions"[Mesh])) OR "Inappropriate Prescribing"[Mesh]) Filters: **Abstract; published in the last 10 years; Aged: 65+ years**	331	06:11:39
#17	Add	Search (((**"Nursing"[Mesh]) OR (nursing intervention or nursing interventions))) AND (((**"Medication Errors"[Mesh]) OR ("Drug-Related Side Effects and Adverse Reactions"[Mesh])) OR "Inappropriate Prescribing"[Mesh]) Filters: **published in the last 10 years; Aged: 65+ years**	355	06:11:28
#16	Add	Search (((**"Nursing"[Mesh]) OR (nursing intervention or nursing interventions))) AND (((**"Medication Errors"[Mesh]) OR ("Drug-Related Side Effects and Adverse Reactions"[Mesh])) OR "Inappropriate Prescribing"[Mesh]) Filters: **published in the last 10 years**	1244	06:11:12
#15	Add	Search (((**"Nursing"[Mesh]) OR (nursing intervention or nursing interventions))) AND (((**"Medication Errors"[Mesh]) OR ("Drug-Related Side Effects and Adverse Reactions"[Mesh])) OR "Inappropriate Prescribing"[Mesh])	2286	06:11:05
#14	Add	Search ("Nursing"[Mesh]) OR (nursing intervention or nursing interventions)	392047	06:10:50
#13	Add	Search (("Medication Errors"[Mesh]) OR ("Drug-Related Side Effects and Adverse Reactions"[Mesh])) OR "Inappropriate Prescribing"[Mesh]	116240	06:10:35
#12	Add	Search nursing intervention or nursing interventions	216456	06:10:08
#11	Add	Search "Nursing"[Mesh]	240631	06:09:41
#8	Add	Search "Inappropriate Prescribing"[Mesh]	1978	06:09:18
#5	Add	Search "Drug-Related Side Effects and Adverse Reactions"[Mesh]	103312	06:07:50
#3	Add	Search "Medication Errors"[Mesh]	14298	06:07:32

ANHANG C: TABELLARISCHE ÜBERSICHTEN

Autoren, Jg., Land (nach APA-Style)	Zielsetzung und Design	Setting und Sample	Verwendetes Instrumente Interventionen	Wichtigste Ergebnisse	Stärken / Schwächen Evidenzlevel
Bergqvist, M., Ulfvarson, J., & Andersén Karlsson, E. (2009) Schweden	**Ziel:** Das Ziel der Studie war es, zu evaluieren, ob eine spezifische Schulung zum Thema «klinische Pharmakologie» die Qualität der medikamentösen Therapie bei älteren Patient/-innen verbessern kann. **Design:** Prä-Post-Studie	**Sample:** Es wurden 460 Patient/-innen bewertet. Davon waren 210 in der Kontrollgruppe (KG) und 250 in der Interventionsgruppe (IG). Beide Gruppen waren in ihren Charakteristika ähnlich. Durchschnittsalter: 80.3 Jahre. **Setting:** Abteilung mit 22 Betten, in einem grossen Spital in Stockholm Pro Jahr ca. 1750 Patient/-innen, 36 Pflegefachpersonen (PP) auf dieser Abteilung tätig Datenerhebung: Juli 2006 bis Dezember 2006.	**Instrumente:** Keine Instrumente erwähnt **Interventionen** Es wurde allen PP eine eintägige Schulung zum Thema «klinische Pharmakologie» angeboten -> 90% der PP nahmen teil (32 von 36). Es wurde Wissen weitergegeben und Tools vorgestellt, die bei der Identifizierung von medikamentenabhängigen Problemen helfen sollten. Tool1: Symptom Assessment Form (SYM); Fragen, zu häufigen Symptomen, welche durch Medikamente ausgelöst werden. Tool2: Zugang zu einer Web-Applikation, die durch die Berechnung der Kreatinin Clearance, die Nierenfunktion einschätzt. Tool3: Zugang zur Janus Web Applikation (JWA); hilft bei der Bestimmung von Medikamenteninterkationen.	Wiedereintritt in den Spital: Es gab keinen signifikanten Unterschied zu diesem Thema (p=0.86). In der IG wurden 94 Patient/-innen nach einem Austritt wieder aufgenommen, in der KG lag dieser Wert bei 76. Auftreten von unangemessener Medikation: In der KG wurden bei 37 Patient/-innen ein oder mehrere unangemessene Medikamente gefunden, in der IG 43; kein signifikanter Unterschied (p=0.90). Gesamthaft waren 102 unangemessene Medikamente in der IG und KG verabreicht worden. Medikamentenbezogene Probleme (drug related problem DRP): Bei 73 von 250 Patient/-innen wurde eine Medikamentenüberprüfung gemacht. Durch die Tools konnten 86 medikamentenbezogene Probleme bei 53 Patient/-innen entdeckt werden, die ansonsten durch die normale Pflege untergegangen wären.	**Stärken:** *Ethik erwähnt *Power eingehalten *Ein-/Ausschlusskriterien wurden genannt **Schwächen:** *Prä-post Studie *Keine Instrumente erwähnt *Durchführung nur in einem Spital *Um den Wiedereintritt in den Spital statistisch zu prüfen, war das Sample zu klein **Evidenzlevel:** **2b** (Behrens & Langer, 2016)

Schlussfolgerung für die Abschlussarbeit in Bezug auf die Fragestellung
Teilweise anwendbar, da nur im Spital durchgeführt und keine signifikanten Ergebnisse. Intervention jedoch kostgünstig und auf CH-Gesundheitssystem anwendbar.

Autoren, Jg., Land (nach APA-Style)	**Zielsetzung und Design**	**Setting und Sample**	**Verwendetes Instrumente Interventionen**	**Wichtigste Ergebnisse**	**Stärken / Schwächen Evidenzlevel**
Blozik, E., Born, A. M., Stuck, A. E., Benninger, U., Gillmann, G., & Clough-Gorr, K. M. (2010). Schweiz	**Ziel:** Das Ziel dieser Studie war es, anhand der Beers-Kriterien die unangemessenen Medikationen in einem Pflegeheim zu reduzieren. Diese Intervention wurde vom Pflegefachpersonal durchgeführt. **Design:** Prä-Post-Studie	**Sample:** Bewohner/-innen, welche über 60 Jahre alt waren. Anfangs der Studie waren 173 Teilnehmende gemeldet, mit einem Durchschnittsalter vor der Intervention von 80.3±8.8 Jahren. **Setting:** Pflegeheim im Kanton Bern, 204 Betten. Datenerhebung: Mai 2006 bis August 2007.	**Instrumente:** Keine erwähnt **Interventionen:** Die Intervention umfasste vier Schlüsselelemente: (i) Anpassung der Beers-Kriterien an das Schweizer Umfeld (ii) unangemessene Medikationsidentifikation: anhand der Beers-Kriterien wurden die Medikamentenlisten der Bewohner/-innen mit der Beers-Liste verglichen, unangemessene Medikamente wurden entdeckt, gekennzeichnet und niedergeschrieben. (iii) unangemessenes Medikationsabbruchsystem: Anhand der Kennzeichnungen und Notizen konnten die Pflegefachpersonen eine mündliche Empfehlung den behandelnden Ärzten/-innen abgeben, die betroffenen Medikamente zu stoppen und Alternativen zu verordnen. Falls das betroffene Medikament nach zwei Monaten weiterhin verordnet wurde, erinnerten die Pflegefachpersonen die behandelnden Ärzte/-innen nochmals. (iv) Mitarbeiterschulung: Die Ärzte/-innen und Pflegestationsleitungen wurden einmalig	Die Anzahl an unangemessenen Medikamentenverordnungen sank signifikant von 14.5% (CI95% 9.2; 19.7) [25/173] vor der Intervention auf 2,8% (CI95% 0.4; 5.3) [5/178] nach der Intervention. Die Bewohner/-innen hatten ein fast fünffach verringertes Risiko einer unangemessenen Medikamentenverordnung nach der Intervention (RR=0.2; CI95% 0.06; 0.5). Das Risiko einer unangemessenen Medikamentenverordnung stieg in der Einjahres-Folgeperiode nicht signifikant auf 4.4% (CI95% 1.4; 7.4) (RR=1.6; CI95% 0.5; 6.1). Das Risiko einer unangemessenen Medikamentenverordnung zeigte ein Jahr nach der Intervention einen statistisch signifikanten Rückgang (RR=0.3; CI95% 0.1; 0.7). Nach der Intervention wurde circa ein Drittel aller unangemessenen Medikamente ohne Ersatz gestoppt. Circa die Hälfte der unangemessenen Medikamente wurde durch einen angemessenen Ersatz aus der Beers Liste ausgewechselt.	**Stärken:** *Ethik berücksichtigt *Anpassung an das Schweizer Gesundheitswesen **Schwächen:** *Nur in einem Pflegeheim durchgeführt *Prä-post Studie *keine Ein- / Ausschlussrkiterien gennannt *kleines Sample, Power wurde nicht berechnet **Evidenzlevel:** **2b** (Behrens & Langer, 2016)

			während einer Stunde über die Prinzipien der unangemessenen Medikation informiert wie auch über die ganze Intervention und Anwendung der Beers-Kriterien. Die Stationsleitungen waren anschliessend zuständig, ihr Team während einer weiteren einstündigen Sitzung darauf vorzubereiten.		
Schlussfolgerung für die Abschlussarbeit in Bezug auf die Fragestellung: Sehr gut umsetzbar im Schweizer Gesundheitswesen, da die Studie in einem Schweizer Setting durchgeführt wurde. kostengünstig					

Autoren, Jg., Land (nach APA, Style)	**Zielsetzung und Design**	**Setting und Sample**	**Verwendetes Instrumente Interventionen**	**Wichtigste Ergebnisse**	**Stärken / Schwächen Evidenzlevel**
Ching, J. M., Williams, B. L., Idemoto, L. M., & Blackmore, C. C. (2013). USA	**Ziel:** Ziel war es, zu evaluieren, ob Lean Management zu einer Reduktion der Medikationsfehler beitragen kann. Dies wurde anhand des «perfekte Dosis» Scores, der Medikationsfehler und an der Adhärenz der sechs Sicherheitsvorschriften gemessen. **Design:** Prä-Post-Studie	**Sample:** 2139 Patient/-innen (= 9244 verteilte Medikamente) Durchschnittsalter: 63 Jahre (18-110). **Setting:** Virginia Mason Medical Center (USA), Spital mit 13 Abteilungen (=336 Betten) Datenerhebung: während 21 Monaten, von Januar 2010 bis September 2011.	**Instrumente:** Wurden nicht genannt **Interventionen** Um die Problemfelder anzugehen und zu verbessern, wurden die Mitarbeitenden bei ihrer täglichen Arbeit beobachtet. Es wurden time-motion Studien gemacht, um herauszufinden, wie viele Schritte, wie viel Zeit die Pflegefachpersonen in etwa bei der Medikamentenverabreichung brauchen. Zudem wurden Patient/-innen, wie auch Mitarbeiter verschiedener Berufe nach ihren Ideen und Vorschlägen zu verschiedenen Problemfeldern befragt. Anhand all dieser Rückmeldungen und Erkenntnisse wurden folgende Veränderungen umgesetzt: Verbesserung des Aussehens / Layout des Medikationsraumes (kleine Veränderungen am Raum sowie U-förmige Arbeitsfläche → weniger laufen, wenn die Medikamente vorbereitet werden) Visuelle Kontrolle (Schild «nicht-Rede-Zone» sowie eine rote Linie am Boden um das Areal zu kennzeichnen → PP können sich auf	Die Verstösse gegen die Sicherheitsvorschriften reduzierten sich signifikant (p<0.001) von 83 Verstösse/100 Medikamente auf 42 Verstösse/100 Medikamente. Dies entspricht einer absoluten Risikoreduktion von 42 Verstösse/100 Medikamente (CI95% 35; 48). Die Medikationsverabreichungsfehler reduzierten sich signifikant (p<0.001) von 10.3 Fehler/100 Medikamente auf 2.8 Fehler/100 Medikamente. Dies entspricht einer absoluten Risikoreduktion von 7.5 Fehler/100 Medikamente (CI95% 5; 10). Die «perfekte Dosis» konnte signifikant (p<0.001) von 37/100 Medikamente auf 68/100 Medikamente gesteigert werden. Dies entspricht einer absoluten Risikoreduktion von 31/100 Medikamente (CI95% 27; 35).	**Stärken:** *grosses Sample *Ethik berücksichtigt **Schwächen:** *Testung in nur einem Spital *Prä-post Studie *keine Ein-/ Ausschlusskriterien genannt *Power wurde nicht berechnet **Evidenzlevel:** **2b** (Behrens & Langer, 2016)

			die Medikamente konzentrieren; zudem eine Leuchte vor dem Medikationsraum, die automatisch einschaltet, falls jemande den Raum betritt -> andere PP können somit ihre Tätigkeiten anpassen) Arbeit standardisieren (PP müssen den sechs Sicherheitsvorschriften folgen → 1. Medikament mit der Medikationsliste vergleichen 2. Medikament von der Vorbereitung bis zur Verabreichung hin beschriftet lassen 3. zwei Arten der Patientenidentifikation überprüfen 4. Medikament dem Patient/-innen erklären 5. Medikament direkt nach der Abgabe «verabreicht» markieren 6. Den ganzen Prozess vor Unterbrechungen/Ablenkungen schützen) «Do vs. Do not Do» Poster (aufgehängt in allen Abteilungen, zudem «jeder Patient, jedes Medikament, jede Zeit» → aufzeigen der Sicherheitsvorschriften)		
Schlussfolgerung für die Abschlussarbeit in Bezug auf die Fragestellung Teilweise anwendbar, da nur im Spital durchgeführt, wurde nicht spezifisch auf ältere Patient/-innen bezogen, das Durchschnittsalter liegt leicht unterhalb des vorgegebenen Alters von 65 Jahren.					

Autoren, Jg., Land (nach APA, Style)	**Zielsetzung und Design**	**Setting und Sample**	**Verwendetes Instrumente Interventionen**	**Wichtigste Ergebnisse**	**Stärken / Schwächen Evidenzlevel**
Ching, J. M., Williams, B. L., Idemoto, L. M., & Blackmore, C. C. (2014). USA	**Ziel:** Ziel der Studie war es, die Wirksamkeit der Implementierung von Medikamenten-verab-reichung via Barcode Scanning zusammen mit den Jidoka Prinzipien (Teil des Lean Programmes / Managements) zu evaluieren. **Design:** Kohortenstudie	**Sample:** 3617 Patient/-innen, davon 54% Frauen, Durchschnittsalter 64 Jahre (zw. 18-110). gesamthaft 16`149 verteilte Medikamente, Durchschnittsmedikation: 3.8 (±3.2)/Pat. **Setting:** Virginia Mason Medical Center (USA), Spital mit 13 Abteilungen (=336 Betten) Datenerhebung: zw. Januar 2010 und Dezember 2012.	**Instrumente:** Keine genannt **Interventionen:** Als erstes wurden die Stärken beider Seiten (Mensch und Maschine: Barcode Scanner) evaluiert (Mensch: Caring und unterstützende Haltung; Maschine: repetitive Sicherheitschecks). Anschliessend wurde durch diverse Tests, Testversuche, Feedbacks und Nachforschungen herausgefunden, wie sich die Maschine am besten in den menschlichen Ablauf integrieren lässt (z.B. bei falschem Code wird PP darauf hingewiesen, kann dann aber s/s entscheiden ob mit der geplanten Medikation weitergefahren wird oder nicht = Prinzipien von Jidoka → Flexibilität einbauen). Es wurde zudem festgelegt, welche Codes zu scannen waren und wie mit speziellen Medikamenten zu verfahren sei. Als letztes wurde bei regelmässigen Treffen Probleme betreffend des Barcode Scanners angegangen und verbessert.	Die Anzahl der Verstösse gegen die Sicherheitsvorkehrungen konnten signifikant (p<0.001) von 54.8 ±77.0/100 Medikamentendosen auf 29.0 ±51.7 Verstösse/100 Medikamentendosen reduziert werden. Dies entspricht einer absoluten Risikoreduktion von 25.8 pro 100 Dosen (CI 95% 23.7; 27.9). Medikationsfehler reduzierten sich signifikant (p<0.001) von 5.9 ±25.5/100 Medikamente auf 3.0 ±18.2/100 Medikamente, was einer absoluten Risikoreduktion von 2.9 Fehlern/100 Dosen entspricht (CI 95% 2.2; 3.6). Nach der Intervention konnte in vier der acht Medikationsverabreichungsfehler (falsches Medikament, falsche Verabreichungsart, falsche Zeit, Medikament nicht vorhanden) eine signifikante Reduktion (p< 0.001) erreicht werden.	**Stärken:** *grosses Sample *Ethik berücksichtigt **Schwächen:** *Durchführung in nur einem Spital *prä-post Studie *Power nicht berechnet **Evidenzlevel:** **2b** (Behrens & Langer, 2016)
Schlussfolgerung für die Abschlussarbeit in Bezug auf die Fragestellung Teilweise anwendbar, da nur im Spital durchgeführt. Die Intervention wurde nicht spezifisch auf ältere Patient/-innen bezogen, das Durchschnittsalter stimmt jedoch mit dem der Fragestellung überein. Nicht spezifisch auf ältere Menschen.					

Autoren, Jg., Land (nach APA, Style)	**Zielsetzung und Design**	**Setting und Sample**	**Verwendetes Instrumente** **Interventionen**	**Wichtigste Ergebnisse**	**Stärken / Schwächen** **Evidenzlevel**
Henneman, E. A., Tessier, E. G., Nathanson, B. H., & Plotkin, K. (2014). USA	**<u>Ziel:</u>** Das Ziel war, zu evaluieren ob ein standardisierter Ansatz zur Erfassung der Medikamentengeschichte einen Einfluss auf die Genauigkeit der Medikationsliste bei der Aufnahme hat. **<u>Design:</u>** Mixed-Method-Design	**<u>Sample:</u>** Phase 1: 16 Pflegestudierende nahmen teil. Diese waren im letzten Ausbildungsjahr ihres Bachelors. Phase 2: Gesamthaft 100 Patient/-innen (je 50 in prä- und post-Intervention), Durchschnittsalter: Prä-Intervention: 68.1 Jahre Post-Intervention: 69.3 Jahre Phase 3: Wird nicht genannt. **<u>Setting:</u>** Phase 1: Schule für Pflegestudierende Phase 2: In einem Universitätsspital	**<u>Instrumente:</u>** keine genannt **<u>Interventionen:</u>** Phase 1: Das Tool wurde zunächst mit Pflegestudierenden in einem pädagogischen Umfeld anhand von Scheinpatienten und simulierten Szenarien evaluiert. Basierend auf den Ergebnissen dieser Phase der Studie wurde das Tool angepasst und anschließend implementiert. Phase 2: Das verbesserte Tool wurde als laminierte Kopie den Pflegefachpersonen ausgehändigt. Die Pflegefachpersonen erhielten eine eins zu eins Schulung zur Anwendung des Tools. Poster und die Schlüsselkonzepte wurden gut sichtbar an den Wänden der Station angebracht. Phase 3: Um mögliche weitere Verbesserungen am Tool vorzunehmen und um die Zufriedenheit herauszufinden, wurde nach der Intervention ein Fragebogen an die Pflegefachpersonen verteilt. Das Tool besteht aus sechs Fra-	Phase 1: Mit dem Tool verbesserte sich die Genauigkeit der Medikamentenabstimmung signifikant (p=0.01) von 74% auf 87% gesamthaft. In zwei Simulationen konnte die Genauigkeit sogar von 73% auf 100%, bzw. von 67% auf 96% verbessert werden. In den anderen Simulationen wurden keine signifikanten Verbesserungen erzielt. Phase 2: Medikationsfehler betreffend der Medikationsliste konnten um 80% gesenkt werden, waren jedoch nicht signifikant (p= 0.204). Der prozentuale Anteil der Patient/-innen ohne Unstimmigkeiten war mehr als doppelt so hoch in der post-Gruppe als in der prä-Gruppe, von 20% auf 42% gesteigert. Dies entspricht einer signifikanten Steigerung (p=0.017). Phase 3: Das Tool wurde als nützlich empfunden, aber sehr zeitintensiv. Es wurden jedoch keine genauen Zahlen hierzu genannt.	**<u>Stärken:</u>** *Tool wurde auf drei verschiedene Weisen getestet **<u>Schwächen:</u>** *Kleines Sample *kein Power berechnet *Keine Ein-/ Ausschlusskriterien genannt *Keine Zulassung durch Ethikkommission genannt **<u>Evidenzlevel:</u>** **3a** (Behrens & Langer, 2016)

		von 653 Betten und in einem Regionalspital von 93 Betten. Datenerhebung: Zeitpunkt wurde nicht genannt	gepaketen, welche nacheinander erfragt werden müssen. Es fängt mit den Basisdaten an (demographische Daten, Allergien, Diagnosen, Ärzte). Im Schritt zwei und drei werden die Medikamente anhand eines vorgegebenen Schemas erfragt. Falls keine genaueren Daten zu den Medikamenten vorahnden sind, werden diese in Schritt vier weiter vertieft. Als fünfter Schritt werden die allgemeinen Fakten erfragt. Am Ende wird eine Übersicht erstellt.		
Schlussfolgerung für die Abschlussarbeit in Bezug auf die Fragestellung Es wurde nur im Spitalsetting durchgeführt. Es konnten keine signifikanten Verbesserungen betreffend die Medikationsfehler während der Medikamentenerfassung festgestellt werden. Jedoch wurde die Medikationsliste viel genauer.					

Autoren, Jg., Land (nach APA, Style)	**Zielsetzung und Design**	**Setting und Sample**	**Verwendetes Instrumente** **Interventionen**	**Wichtigste Ergebnisse**	**Stärken / Schwächen Evidenzlevel**
Pitkälä, K. H., Juola, A.-L., Kautainen, H., Soini, H., Finne-Soveri, U. H., Bell, J. S., & Björkman, M. (2014). Finnland	**<u>Ziel</u>** Ziel der Studie war es, den Effekt von Schulungen der Pflegefachpersonen bei möglichen vorkommenden schädigenden Medikamentennutzungen zu evaluieren. **<u>Design:</u>** RCT	**<u>Sample:</u>** 227 Bewohner/-innen (Einschlusskriterien: siehe kritische Beurteilung) Durchschnittsalter: 83 Jahre. **<u>Setting:</u>** 20 Stationen in Pflegeheimen in Helsinki. Datenerhebung: Zeitpunkt wurde nicht genannt.	**<u>Instrumente:</u>** Keine genannt **<u>Interventionen</u>** Die Intervention war eine Schulung, bestehend aus zweimal vier Stunden Training für diplomierte Pflegefachpersonen zum Thema schädigende Medikation (Definition nach den Beers-Kriterien). Die erste vier Stunden Session basierte auf einer Lektüre zu diesem Thema. Die Pflegefachpersonen wurden zudem ermutigt, über ihre Erfahrungen zum Thema der medikamentenabhängigen Probleme zu sprechen. Es wurde eine Liste mit schädigenden Medikamenten vorgestellt sowie mögliche Alternativen dazu. Es wurde zudem über die Medikation bei Patient/-innen mit Niereninsuffizienz diskutiert. In der zweiten vier Stunden Session wurden Fallstudien genauer betrachtet. Anhand der «problem-based-learning» Prinzipien erörterten die Pflegefachpersonen medikamentenabhängige Probleme. Die Pflegefachpersonen wurden	Die Häufigkeit schädigender Medikamente reduzierte sich signifikant (p=0.009) nach 12 Monaten um -11.7 (CI95% -20.5; -2.9) in der Interventionsgruppe (IG). In der Kontrollgruppe (KG) gab es mit +3.4 (CI95% -3.7; 10.6) keine signifikanten Änderungen (p=0.34). Betreffend der Häufigkeit von vorkommender schädigender Medikamentennutzung konnte eine signifikante Änderung (p=0.022) zwischen IG und KG erbracht werden. Durch die Intervention konnte in der IG die durchschnittliche Anzahl an Medikamenten signifikant (p=0.0024) um -0.43 (CI95% -0.15; -0.71) verringert werden, blieb in der KG jedoch stabil mit +0.11 (p=0.27) (CI95% -0.09; 3.1). Die Differenz der durchschnittlichen Anzahl an Medikamenten war zwischen IG und KG signifikant (p=0.0035).	**<u>Stärken:</u>** *grosses Sample *Ein-/ Ausschlusskriterien genannt *Ethik geprüft *Power eingehalten *Limiten erwähnt **<u>Schwächen:</u>** - **<u>Evidenzlevel:</u>** **1b** (Behrens & Langer, 2016)

			dazu ermuntert ihre eigenen Prozeduren und mögliche Verbesserungen zu reflektieren und zu diskutieren. Anschliessend wurde eine Liste der schädigenden Medikamente an alle beteiligten Stationen der Interventionsgruppe ausgehändigt. Die Pflegefachpersonen wurden aufgefordert diese Liste und ihr Wissen dazu zu gebrauchen, um mögliche medikamentenbedingte Probleme zu identifizieren und den behandelnden Ärzten/-innen mitzuteilen.		
Schlussfolgerung für die Abschlussarbeit in Bezug auf die Fragestellung Gut und einfach anwendbar. Intervention wurde jedoch nur in Pflegeheimen getestet, nicht auch im Spital.					

Autoren, Jg., Land (nach APA-Style)	**Zielsetzung und Design**	**Setting und Sample**	**Verwendetes Instrumente** **Interventionen**	**Wichtigste Ergebnisse**	**Stärken / Schwächen Evidenzlevel**
Poon, E. G., Keohane, C. A., Yoon, C. S., Ditmore, M., Bane, A., Levtzion-Korach, O., … Gandhi, T. K. (2010) Grossbritannien	**Ziel:** Das Ziel war es, den Effekt des elektronischen Medikamentenverabreichungssystems (eMAR) zu evaluieren, gemessen an den Medikationsverabreichungsfehlern, den möglichen unerwünschten Medikamentenwirkungen und den Übertragungsfehlern. **Design:** Prä-Post-Studie	**Sample:** 1’726 Teilnehmende, dies ergibt 14'041 verabreichte Medikamente. Durchschnittsalter: Medizinische Abteilung: prä: 64.3±17.1; post 64.6±16.5 Chirurgische Abteilung: prä 58.5±17.0; post 58.4±17.8 Intensivstation: prä 62.4±16.7; post 61.3±15.3 **Setting:** Universitätsspital mit 735 Betten, durchgeführt auf medizinischen, chirurgischen und Intensivstationen.	**Instrumente:** Keine genannt **Interventionen:** Anfangs erhielten die Pflegenden eine Schulung à vier Stunden, in der das elektronische Medikamentenverabreichungssystem (eMAR) vorgestellt wurde. Die Medikamente werden elektronisch eingelesen (durch Ärzte/-innen). Die zu verabreichenden Medikamente erscheinen den Pflegefachpersonen elektronisch auf dem Bildschirm. Der Medikamentenbarcode und der Barcode des Patientenarmbandes werden daraufhin vor der Verabreichung des Medikaments gescannt und falls richtig, automatisch dokumentiert. Falls ein Fehler vorliegt (z.B. falsche Dosis), wird eine Warnung abgegeben. Das System warnt die Pflegefachpersonen ebenfalls, wenn eine Medikation überfällig ist.	Es wurde gesamthaft 14’041 Medikamentenverabreichungen und 3’082 Medikamenteneinträge beobachtet. Es wurden 776 nicht-zeitbedingte Medikamentenabgabefehler auf den Abteilungen ohne eMAR Barcode Scanning (entspricht einer Fehlerrate von 11.5%) und 495 Fehler auf Abteilungen mit eMAR Barcode Scanning (entspricht einer Fehlerrate von 6.8%) beobachtet. Dies entspricht einer relativen Risikoreduktion von RR= -41.4% (CI95% -34.2; -47.6) und ist somit signifikant (p<0.001). Die Anzahl der möglichen unerwünschten Medikamentenwirkungen in Zusammenhang mit den nicht-zeitbedingten Medikamentenabgabefehlern sank signifikant (p<0.001) von 213 (entspricht 3.1%) ohne Verwendung eMAR Barcode Scanning, auf 114 (entspricht 1.6%) durch die Verwendung des Barcode Scanning. Dies entspricht einer relativen Risikoreduktion von RR= -50.8% (CI95% -39.1; -61-7). Die Anzahl der zeitbedingten Medikamentenabgabefehler fiel signifikant (p=0.001) von 1’126 (entspricht 16.7%) auf 891 (entspricht 12.2%) mit dem eMAR Barcode Scanning. Dies entspricht einer relativen Risikoreduktion von RR= -27.3% (CI95% -21.0; -33.8). Die Anzahl der möglichen unerwünschten	**Stärken:** *Grosses Sample *Limitationen genannt **Schwächen:** *keine Angaben zur Ethik *Durchführung nur an einem Standort *Prä-Post Studie *Power nicht berechnet *keine Ein-/ Ausschlusskriterien genannt **Evidenzlevel:** **2b** (Behrens & Langer, 2016)

				Medikamentenwirkungen in Zusammenhang mit den zeitbedingten Medikamentenabgabefehlern verringerte sich nicht signifikant (p=0.44) von 34 (entspricht 0.5%) ohne eMAR Barcode Scanning auf 30 (entspricht 0.4%) mit Barcode Scanning. Dies entspricht einer relativen Risikoreduktion von RR= -18.9% (CI95% -60.4; 25.5).	
Schlussfolgerung für die Abschlussarbeit in Bezug auf die Fragestellung: Die Intervention wurde nur im Spital durchgeführt. Das Durchschnittalter bei dieser Studie liegt unter dem Alter in der Fragestellung. Die Studie wird trotzdem analysiert, da die Abweichung minimal ist und die Intervention eine wichtige Massnahme im zukünftigen Pflegealltag spielen könnte. Die Implementierung ist anfangs zeitintensiv, die möglichen Nutzen überwiegen jedoch.					

Autoren, Jg., Land (nach APA, Style)	**Zielsetzung und Design**	**Setting und Sample**	**Verwendetes Instrumente** **Interventionen**	**Wichtigste Ergebnisse**	**Stärken / Schwächen Evidenzlevel**
Van Welie, S., Wijma, L., Beerden, T., Van Doormaal, J., & Taxis, K. (2016). Niederlande	**Ziel:** Das Ziel war, den Effekt von Warnsymbolen und Schulungen auf die Häufigkeit von irrtümlich gemörserten Medikamenten zu evaluieren. **Design:** Prä-Post-Studie	**Sample:** In der prä-Gruppe wurden 164 Patient/-innen bewertet, in der post-Gruppe waren es 150. Dies entspricht 681 Medikamentenabgaben in der prä-Gruppe, bzw. 636 in der post-Gruppe. Beide Gruppen waren in ihren Charakteristika ähnlich. Durchschnittsalter: 81.6 Jahre **Setting:** 18 Stationen in drei niederländischen Pflegeheimen (gesamthaft 200 Betten) Datenerhebung: November 2013 bis Dezember 2013 und März	**Instrumente:** Keine genannt **Interventionen** Durch das automatische Tablettenausgabe- und Verpackungssystem wurden Warnsymbole auf die Verpackungen gedruckt. Ein positives Symbol um aufzuzeigen, dass das Medikament gemörsert werden kann, ein negatives wenn dies nicht indiziert war. Zudem wurde eine 20-minütige Schulung durch eine/n Apotheker/in gegeben, in der die Einführung der neuen Symbole erklärt wurden, Informationen über mögliche Medikamente gegeben wurden, sowie mögliche Alternativen zum Mörsern aufgezeigt wurden. Abschliessend wurde den Mitarbeitern ein digitaler Newsletter zugesandt, der den Inhalt der Schulung auf einer Seite zusammenfasste. Es wurden zusätzlich Poster mit der Erklärung der zwei Symbolen auf den Stationen angebracht. Diese sollten als Erinnerungsstütze dienen.	Die Anzahl an irrtümlich gemörserten Medikamenten konnte von 21 auf 3 signifikant reduziert werden (von 3.1% auf 0.5%). Dies entspricht einer relativen Risikoreduktion von 0.15 (CI95% 0.05; 0.51). Die Anzahl an Patient/-innen mit gemörserten Medikamenten reduzierte sich nicht signifikant (p=0.20) von 19 vor der Intervention auf 11 nach der Intervention (von 11.6% auf 7,3%). Das irrtümliche Zermörsern von Medikamenten wurde vor der Intervention auf 11 von 18 Stationen beobachtet (=61%), nach der Intervention lag dieser Wert bei 3 von 18 Stationen (=17%).	**Stärken:** *Power eingehalten *Limitationen wurden genannt **Schwächen:** *Prä-Post Studie *Keine Ein-/ Ausschlusskriterien genannt *Keine Zulassung der Ethikkommission erwähnt **Evidenzlevel:** **2b** (Behrens & Langer, 2016)

		2014			

Schlussfolgerung für die Abschlussarbeit in Bezug auf die Fragestellung
Teilweise anwendbar, da nur in Pflegeheimen durchgeführt. Ansonsten scheint die Intervention jedoch mit wenig Aufwand Erfolg zu haben und ist für die Fragestellung geeignet.

ANHANG D: KRITISCHE BEURTEILUNGEN

Kritische Beurteilung Bergqvist et al (2009)

- nach Behrens und Langer (2016)

Artikel:
Bergqvist, M., Ulfvarson, J., & Andersén Karlsson, E. (2009). Nurse-led medication reviews and the quality of drug treatment of elderly hospitalized patients. European Journal of Clinical Pharmacology, 65(11), 1089–1096. https://doi.org/10.1007/s00228-009-0728-2

Es handelt sich hierbei um eine Prä-Post-Studie.

Glaubwürdigkeit	
Wie wurden die Teilnehmenden rekrutiert und den Untersuchungsgruppen zugeteilt?	Es wurden alle Patient/-innen, die den Einschlusskriterien entsprachen, aufgenommen (Einschlusskriterien: über 65 Jahre, behandelt während länger als drei Monaten). Als Ausschlusskriterium galt eine geschützte Identität/Akte. Die Zuteilung in die Untersuchungsgruppen fand nach dem Stationierungszeitraum statt; Patient/-innen, die während Oktober bis Dezember 2006 stationiert waren gehörten zur Interventionsgruppe (IG), Patient/-innen, die während Juli bis September 2006 stationiert waren, gehörten zur Kontrollgruppe (KG).
Wie viele Patient/-innen, die anfangs in die Studie aufgenommen wurden, waren am Ende noch dabei?	Nicht anwendbar, da es sich um eine prä-post Studie handelt.
Waren die Teilnehmenden, das Personal und die Untersuchenden verblindet?	Die Teilnehmenden waren verblindet, das Personal und die Untersuchenden nicht.
Waren die Untersuchungsgruppen zu Beginn der Studie ähnlich?	KG und IG waren zu Beginn der Studie sehr ähnlich was das Alter und die Anzahl an Medikamenten angeht. Die zwei Gruppen unterschieden sich in den Werten der Niereninsuffizienz und der versteckten Niereninsuffizienz.

Wurden die Untersuchungsgruppen – abgesehen von der Intervention – gleich behandelt?	Nicht anwendbar, da es sich um eine prä-post Studie handelt.
Wurden alle Teilnehmenden in der per Randomisierung zugeteilten Gruppen bewertet?	Nicht anwendbar, da es sich um eine prä-post Studie handelt.
War die Grösse der Stichprobe ausreichend gewählt, um einen Effekt nachweisen zu können?	Ein Power für die Messung der Daten bei «unangemessene Medikation» wurde berechnet und eingehalten. Ein Power um die Wiedereintritte in den Spital zu berechnen, wurde auch errechnet, jedoch nicht eingehalten. Daher ist die Stichprobe nur zum Teil ausreichend gross gewählt worden.
Stehen die Ergebnisse im Einklang mit anderen Untersuchungen auf diesem Gebiet?	Ja, Medikamentenabgleiche, geführt durch Pflegefachpersonen, können Wiedereintritte ins stationäre Gesundheitswesen verringern, wie andere Studien gezeigt haben.
Aussagekraft	
Wie ausgeprägt war der Behandlungseffekt?	Die Behandlungseffekte waren nicht signifikant. Wiedereintritt in den Spital: In der IG wurden 94 Patient/-innen nach einem Austritt wieder aufgenommen, in der KG lag dieser Wert bei 76. Auftreten von unangemessener Medikation: In der KG wurden bei 37 Patient/-innen ein oder mehrere unangemessene Medikamente gefunden, in der IG 43. Gesamthaft waren 102 unangemessene Medikamente in der IG und KG verabreicht worden. Medikamentenbezogenen Probleme:

	Bei 73 von 250 Patient/-innen wurde die Medikamentenüberprüfung gemacht. Durch die Tools konnten 86 medikamentenbezogene Probleme bei 53 Patient/-innen entdeckt werden, die ansonsten in der normalen Pflege untergegangen wären.
Sind die unterschiedlichen Ergebnisse nicht nur auf einen Zufall zurück zu führen?	Nein, die Ergebnisse sind nicht auf einen Zufall zurück zu führen. Wiedereintritt in Spital: *p*=0.86 Auftreten von unangemessener Medikation: *p*= 0.90
Wie präzise sind die Ergebnisse?	CI wurde nirgends erwähnt. Es lassen sich also keine Schlüsse über die Präzision der Ergebnisse ziehen.
Anwendbarkeit	
Sind die Ergebnisse auf meine Patient/-innen übertragbar?	Ja, die Patient/-innen haben das gleiche Alter, jedoch wurde die Studie nur im Spitalsetting durchgeführt, nicht im Pflegeheim.
Wurden alle für mich wichtigen Ergebnisse betrachtet?	Ja.
Ist der Nutzen die möglichen Risiken und Kosten wert?	Schaden wird mit dieser Intervention keine zugefügt. Ob sich die finanziellen Bemühungen bei keiner signifikanten Änderung lohnen, ist fraglich.

- Die Studie wurde von der Ethikkommission des Karolinska Institut in Stockholm, Schweden, zugelassen.

Kritische Beurteilung Blozik et al. (2010)

- nach Behrens und Langer (2016)

Artikel:
Blozik, E., Born, A. M., Stuck, A. E., Benninger, U., Gillmann, G., & Clough-Gorr, K. M. (2010). Reduction of inappropriate medications among older nursing-home residents: A nurse-led, prepost-design, intervention study. *Drugs and Aging*, *27*(12), 1009–1017. https://doi.org/10.2165/11584770-000000000-00000

Es handelt sich hierbei um eine Prä-Post-Studie.

Glaubwürdigkeit	
Wie wurden die Teilnehmenden rekrutiert und den Untersuchungsgruppen zugeteilt?	Es wurden alle Bewohner/-innen, die über 60 Jahre alt waren, rekrutiert. Die gleichen Bewohner/-innen nahmen jeweils in der prä- und in der post-Gruppe teil (ausser sie verstarben während der Untersuchungsperiode). Daher gibt es keine Zuteilung.
Wie viele Patient/-innen, die anfangs in die Studie aufgenommen wurden, waren am Ende noch dabei?	Anfangs waren es 173 Bewohner/-innen, ein Teil davon verstarb und es kamen neue Bewohner/-innen dazu. Ein Jahr nach der Intervention waren es somit 181 Bewohner/-innen. Diese Frage ist hier nur bedingt anwendbar, da es sich um eine prä-post Studie handelt
Waren die Teilnehmenden, das Personal und die Untersuchenden verblindet?	Die Teilnehmenden waren verblindet, das Personal und die Untersuchenden nicht.
Waren die Untersuchungsgruppen zu Beginn der Studie ähnlich?	Es gab keine signifikanten Unterschiede betreffend die Charakteristika der Gruppe vor der Intervention verglichen mit der Gruppe nach der Intervention.
Wurden die Untersuchungsgruppen – abgesehen von der Intervention – gleich behandelt?	Nicht anwendbar, da es sich um eine prä-post Studie handelt.
Wurden alle Teilnehmenden in der per Randomisierung	Nicht anwendbar, da es sich um eine prä-post Studie handelt.

zugeteilten Gruppen bewertet?	
War die Größe der Stichprobe ausreichend gewählt, um einen Effekt nachweisen zu können?	Die Power wurde nicht berechnet. Die Stichprobe ist mit 173, bzw. 181 Teilnehmenden eher klein gewählt.
Stehen die Ergebnisse im Einklang mit anderen Untersuchungen auf diesem Gebiet?	Es ist eine der ersten Studien, die anhand der Beers Kriterien, angepasst ans Schweizer Gesundheitswesen und durchgeführt durch Pflegefachpersonen, die unangemessenen Medikationen reduziert. Es gibt bereits Studien mit den Beers Kriterien, die dieselben Ergebnisse zeigen, jedoch von Ärzten/-innen durchgeführt wurden. Die Autorinnen antworten daher auf diese Frage mit Ja.
Aussagekraft	
Wie ausgeprägt war der Behandlungseffekt?	Die Anzahl an unangemessenen Medikationsverordnungen sanken von 14.5% (25/173) vor der Intervention auf 2,8% (5/178) nach der Intervention. Die Bewohner/-innen hatten ein fast fünffach verringertes Risiko einer unangemessenen Medikationsverordnung nach der Intervention (RR=0.2). Das Risiko einer unangemessenen Medikationsverordnung stieg in der Einjahres-Folgeperiode nicht signifikant auf 4.4% an (RR=1.6). Das Risiko einer unangemessenen Medikationsverordnung zeigte ein Jahr nach der Intervention einen statistisch signifikanten Rückgang (RR=0.3).
Sind die unterschiedlichen Ergebnisse nicht nur auf einen Zufall zurück zu führen?	Es wurde keinen p-Werte genannt. Die Signifikanz wurde soweit als möglich vom RR und dem Konfidenzintervall abgeleitet. Anzahl an unangemessener Medikationsverordnungen: Signifikantes Ergebnis, da RR=0.2 beim Konfiden-

	zintervall die 1 ausschliesst. Anstieg des Risikos für unangemessene Medikationsverordnungen: Nicht signifikantes Ergebnis, da RR=1.6 beim Konfidenzintervall die 1 einschliesst Risiko einer unangemessenen Medikationsverordnung nach einem Jahr: Signifikantes Ergebnis, da RR=0.3 beim Konfidenzintervall die 1 ausschliesst
Wie präzise sind die Ergebnisse?	Anzahl an unangemessener Medikationsverordnungen ist präzise: CI95% 0.06; 0.5 Anstieg des Risikos für unangemessene Medikationsverordnungen ist eher unpräzise: CI95% 1.4; 7.4 Risiko einer unangemessenen Medikationsverordnung nach einem Jahr ist präzise: CI95% 0.1; 0.7
Anwendbarkeit	
Sind die Ergebnisse auf meine Patient/-innen übertragbar?	Teilweise, da die Intervention nur im Pflegeheim durchgeführt wurde und nicht auch noch im Spitalsetting.
Wurden alle für mich wichtigen Ergebnisse betrachtet?	Ja.
Ist der Nutzen die möglichen Risiken und Kosten wert?	Ja, anfangs ist es bis zur Implementation ein wenig aufwändiger, danach überwiegen jedoch die positiven Seiten.

- Das Studienprotokoll wurde von der lokalen Ethikkommission genehmigt.

Kritische Beurteilung Ching et al. (2013)

- nach Behrens und Langer (2016)

Artikel:
Ching, J. M., Long, C., Williams, B. L., & Blackmore, C. C. (2013). Using lean to improve medication administration safety: In search of the “perfect dose.” Joint Commission Journal on Quality and Patient Safety, 39(5), 195–204. https://doi.org/10.1016/S1553-7250(13)39026-6

Es handelt sich hierbei um eine Prä-Post-Studie.

Glaubwürdigkeit	
Wie wurden die Teilnehmenden rekrutiert und den Untersuchungsgruppen zugeteilt?	Genauer Vorgang der Rekrutierung wurde nicht erwähnt. Gesamthaft waren 13 Stationen des Virginia Mason Hospitals in die Studie involviert. Untersuchungsgruppen: Es wurden die Daten der Patient/-innen vor der Intervention mit den Daten von Patient/-innen nach der Intervention verglichen. Jedoch wurde anschliessend nicht mit der Anzahl an Patient/-innen gerechnet, sondern mit der Anzahl der verabreichten Medikamente.
Wie viele Patient/-innen, die anfangs in die Studie aufgenommen wurden, waren am Ende noch dabei?	Nicht anwendbar, da es sich um eine prä-post Studie handelt.
Waren die Teilnehmenden, das Personal und die Untersuchenden verblindet?	Teilnehmer waren verblindet. Die Untersucher und das Personal nicht. Eine Verblindung wäre in diesem Fall nicht möglich gewesen.
Waren die Untersuchungsgruppen zu Beginn der Studie ähnlich?	Wurde nicht erwähnt. Ist auch nur bedingt anwendbar, da es sich um eine prä-post Studie handelt.
Wurden die Untersuchungsgruppen – abgesehen von der Intervention – gleich behandelt?	Nicht anwendbar, da es sich um eine prä-post Studie handelt.
Wurden alle Teilnehmenden in der per Randomisierung	Nicht anwendbar, da es sich um eine prä-post Stu-

zugeteilten Gruppe bewertet?	die handelt.
War die Größe der Stichprobe ausreichend gewählt, um einen Effekt nachweisen zu können?	Ein Power wurde nirgends erwähnt. Gesamthaft wurden 9244 Medikamente verteilt und beurteilt. Die Grösse der Stichprobe scheint damit ausreichend zu sein.
Stehen die Ergebnisse im Einklang mit anderen Untersuchungen auf diesem Gebiet?	Ja.
Aussagekraft	
Wie ausgeprägt war der Behandlungseffekt?	Verstösse gegen die Sicherheitsvorschriften: Von anfangs 83 Verstösse/100 Medikamente (= pro 100 Medikamente) konnten die Verstösse auf 42 /100 Medikamente reduziert werden. Dies entspricht einer absoluten Risikoreduktion von 42/100 Medikamente. Medikamentenverabreichungsfehler: Konnten von 10.3 Fehler/100 Medikamente auf 2.8 Fehler/100 Medikamente reduziert werden. Dies entspricht einer absoluten Risikoreduzierung von 7.5 Fehler/100 Medikamente. Perfekte Dosis: Einhaltung aller sechs Sicherheitsvorschriften konnte von 37/100 Medikamente auf 68/100 Medikamente gesteigert werde. Dies entspricht einer absoluten Risikoreduzierung von 31.
Sind die unterschiedlichen Ergebnisse nicht nur auf einen Zufall zurück zu führen?	Verstösse gegen die Sicherheitsvorschriften: $p<0.001$ → signifikant Medikamentenverabreichungsfehler signifikant reduziert: $p<0.001$

	perfekte Dosis signifikant gesteigert: *p*<0.001
Wie präzise sind die Ergebnisse?	Bei allen wurde mit einem CI von 95% gerechnet. Ergebnisse sind in den Augen der Autorinnen präzise. Verstösse gegen die Sicherheitsvorschriften: CI95% 35; 48 Medikamentenverabreichungsfehler: CI95% 5; 10 perfekte Dosis: CI95% 27; 35
Anwendbarkeit	
Sind die Ergebnisse auf meine Patient/-innen übertragbar?	Jein… Alter stimmt, Setting im Spital -> Lean wäre sicherlich auch im Pflegeheim anwendbar, wurde aber in dieser Studie nicht getestet.
Wurden alle für mich wichtigen Ergebnisse betrachtet?	Nein. Die ungefähre Kostenzahl wäre von Interesse gewesen und wie Pflegefachpersonen die Lean-Interventionen empfunden haben.
Ist der Nutzen die möglichen Risiken und Kosten wert?	Es gibt hohe Anfangskosten zu überwinden. Die Umgestaltung und Veränderung durch das Lean-Management nimmt viel Zeit und andere Ressourcen in Anspruch. Damit diese Intervention umgesetzt werden kann, muss der Wille zur Veränderung vorhanden. Ist dies der Fall, so kann diese Intervention viel zur Medikationssicherheit beitragen.

- Die Zulassung durch eine Ethikkommission wurde gewährt (erwähnt als Institutional Review Board).

Kritische Beurteilung Ching et al. (2014)

- nach Behrens und Langer (2016)

Artikel:
Ching, J. M., Williams, B. L., Idemoto, L. M., & Blackmore, C. C. (2014). Using Lean "Automation with a Human Touch" to Improve Medication Safety: A Step Closer to the "Perfect Dose." The Joint Commission Journal on Quality and Patient Safety, 40(8), 341–AP3. https://doi.org/10.1016/S1553-7250(14)40045-X

Es handelt sich hierbei um eine Prä-Post-Studie.

Glaubwürdigkeit	
Wie wurden die Teilnehmenden rekrutiert und den Untersuchungsgruppen zugeteilt?	Die genaue Rekrutierung wurde nicht erwähnt, es wurden das Alter (+18 Jahre) und Hospitalisationszeitraum (Januar 2010 bis September 2011) als Einschlusskriterien genannt. Untersuchungsgruppen: Zum Vergleich wurden die Daten der Beobachtungen, die ein Vierteljahr vorher der Intervention stattfanden, genommen (=prä-Gruppe). Als post-Gruppe wurden die Daten von Beobachtungen während der zwei nachfolgenden Jahren genommen.
Wie viele Patient/-innen, die anfangs in die Studie aufgenommen wurden, waren am Ende noch dabei?	Nicht anwendbar, da es sich um eine prä-post Studie handelt.
Waren die Teilnehmenden, das Personal und die Untersuchenden verblindet?	Personal und Untersucher waren nicht verblindet (hätte auch keine Möglichkeit dafür gegeben) Auch die TN waren nicht verblindet, da diese bei der Kontrolle selbst mitgewirkt hatten.
Waren die Untersuchungsgruppen zu Beginn der Studie ähnlich?	Wurde nicht genannt, ist zudem nur bedingt anwendbar, das es sich um eine prä-post Studie handelt.
Wurden die Untersuchungsgruppen – abgesehen von der Intervention – gleich be-	Nicht anwendbar, da es sich um eine prä-post Studie handelt.

handelt?	
Wurden alle Teilnehmenden in der per Randomisierung zugeteilten Gruppe bewertet?	Nicht anwendbar, da es sich um eine prä-post Studie handelt.
War die Größe der Stichprobe ausreichend gewählt, um einen Effekt nachweisen zu können?	Es konnten signifikante Ergebnisse erzeugt werden. Die Grösse der Stichprobe mit 3617 Patient/-innen, bzw. mit 16`149 verteilten Medikamenten scheint angemessen gross zu sein.
Stehen die Ergebnisse im Einklang mit anderen Untersuchungen auf diesem Gebiet?	Ja, Barcode Scanning ist in der USA bereits in der Praxis verankert und hat bewiesenermassen die Anzahl der Medikationsfehler gesenkt. Die Implementierung im Zusammenhang mit Lean, bzw. Jidoka ist jedoch unseres Wissens nach neu und kann somit nicht verglichen werden.
Aussagekraft	
Wie ausgeprägt war der Behandlungseffekt?	Verstösse gegen Sicherheitsvorschriften: Sanken signifikant von 54.8±77.0/100 Medikamente auf 29.0±51.7/100 Medikamente, was einer absoluten Risikoreduktion von 25.8/100 Medikamenten entspricht. Medikamentenverabreichungsfehler: Sanken signifikant von 5.9±25.5/100 verteilte Medikamente auf 3.0±18.2/100 verteilte Medikamente, was einer Risikoreduktion von 2.9/100 verteilte Medikamente entspricht.
Sind die unterschiedlichen Ergebnisse nicht nur auf einen Zufall zurück zu führen?	Verstösse gegen Sicherheitsvorschriften: $p<0.001$ Medikamentenverabreichungsfehler: $p<0.001$
Wie präzise sind die Ergeb-	Bei allen wurde mit einem CI von 95% gerechnet

nisse?	Verstösse gegen Sicherheitsvorschriften: CI95% 23.7; 27.7 Medikamentenverabreichungsfehler: CI95% 2.2; 3.6 Beide Ergebnisse sind in den Augen der Autorinnen präzise.
Anwendbarkeit	
Sind die Ergebnisse auf meine Patienten/innen übertragbar?	Jein… Alter stimmt, Setting im Spital → Lean wäre sicherlich auch im Pflegeheim anwendbar, wurde aber in dieser Studie nicht getestet.
Wurden alle für mich wichtigen Ergebnisse betrachtet?	Ja.
Ist der Nutzen die möglichen Risiken und Kosten wert?	Medikamentenverabreichung/-verteilung mit Barcode Scanning ist sicherlich nützlich. Ob nun zusammen mit Lean, bzw. Jidoka angewendet oder nicht hängt vom Budget der Institution ab. Der Nutzen ist definitiv vorhanden, jedoch muss mit einem ein grosser Arbeits- und Zeitaufwand gerechnet werden. Zudem fallen höhere finanzielle Kosten an, falls das Barcode Scanning zusammen mit dem Lean implementiert werden soll. Der Nutzen ist in diesem Fall abhängig von der Grösse der Institution (je grösser, desto geringer die Gesamtkosten) und den finanziellen Mitteln, die diesen zur Verfügung stehen.

- Die Studie wurde von der Ethikkommission (Institutional Review Board) als Qualitätsverbesserungsintervention angesehen und daher von einer förmlichen Prüfung ausgenommen.

Kritische Beurteilung Henneman et al. (2014)

- nach Behrens und Langer (2016)

Artikel:
Henneman, E. A., Tessier, E. G., Nathanson, B. H., & Plotkin, K. (2014). An evaluation of a collaborative, safety focused, Nurse-Pharmacist intervention for improving the accuracy of the medication history. Journal of Patient Safety, 10(2), 88–94. https://doi.org/10.1097/PTS.0b013e318294890c

Es handelt sich hierbei um eine Studie mit verschiedenen Designs (Mixed-Method-Design).

Glaubwürdigkeit	
Wie wurden die Teilnehmenden rekrutiert und den Untersuchungsgruppen zugeteilt?	Phase 1: Rekrutierung: 16 Pflegestudierende nahmen teil, genauer Ablauf der Rekrutierung wird nicht genannt. Randomisierung der Pflegestudierenden fand statt, wie wird nicht erwähnt (7 in IG, 9 in KG) Phase 2: Rekrutierung der Patient/-innen erfolgte über Nachfrage und Zustimmung auf vier verschiedenen Abteilungen. Diese Probanden wurden anschliessend willkürlich durch einen Nummerngenerator in Untergruppen von 25 Personen eingeteilt (durch Excel Programm), damit eine repräsentative Vertretung beider Spitäler vorhanden war. Phase 3: Wird nicht genannt, nur dass eine Umfrage unter den Pflegeangestellten verteilt wurde
Wie viele Patient/-innen, die anfangs in die Studie aufgenommen wurden, waren am Ende noch dabei?	Phase 1: Es gab nur eine Erhebung → keine Ausfälle. Phase 2: Nicht anwendbar, da es sich um eine prä-post Stu-

	die handelt. Phase 3: Wurde nicht erwähnt
Waren die Teilnehmenden, das Personal und die Untersuchenden verblindet?	Phase 1: Die Teilnehmenden waren nicht verblindet, wäre auch nicht möglich gewesen, da diese, das Tool zur Hand hatten. Die Untersuchenden wurden nicht verblindet, wäre jedoch möglich gewesen. Phase 2: Die Teilnehmenden waren verblindet, ob die Untersucher verblindet wurden, ist nicht nachvollziehbar.
Waren die Untersuchungsgruppen zu Beginn der Studie ähnlich?	Phase 1: Die Ähnlichkeit in der IG und KG der Pflegestudierenden wurde nicht erwähnt. Phase 2: Zwischen der prä und post Gruppe gab es betreffend Geschlecht und demographischen Daten keinen signifikanten Unterschied. Jedoch hatten die Probanden in der post- Gruppe signifikant weniger Medikamente als in der prä-Gruppe. Phase 3: --
Wurden die Untersuchungsgruppen – abgesehen von der Intervention – gleich behandelt?	Phase 1: Ja, wurden ansonsten gleich behandelt. Phase 2: Nicht anwendbar, da es sich um eine prä-post Studie handelt. Phase 3: --
Wurden alle Teilnehmenden	Nicht anwendbar, da es sich um eine prä-post Stu-

in der per Randomisierung zugeteilten Gruppe bewertet?	die handelt.
War die Größe der Stichprobe ausreichend gewählt, um einen Effekt nachweisen zu können?	Phase 1: Power wurde nicht berechnet, es gab jedoch einzelne signifikante Ergebnisse Phase 2: Power wurde nicht berechnet, es gab ein signifikantes Ergebnis. Jedoch sind die Gruppen mit jeweils 50 Teilnehmenden eher gering.
Stehen die Ergebnisse im Einklang mit anderen Untersuchungen auf diesem Gebiet?	Ja, es gibt einige Studien, die auf das gleiche Ergebnis kommen.
Aussagekraft	
Wie ausgeprägt war der Behandlungseffekt?	Phase 1: Es wurde kein Mittelwert genannt, jedoch Prozentzahlen. Mit dem Tool verbesserte sich die Genauigkeit der Medikamentenabstimmung von 74% auf 87% gesamthaft. In zwei Simulationen konnte die Genauigkeit sogar von 73% auf 100%, bzw. von 67% auf 96% verbessert werden. In den anderen Simulationen konnten keine. In den anderen zwei Simulationen konnten keine signifikanten Veränderungen erreicht werden. Phase 2: Es wurden keine Mittelwerte genannt. Medikamentenfehler betreffend der Medikationsliste konnten um 80% gesenkt werden, jedoch nicht signifikant (p-Wert siehe unten P1). Der prozentuale Anteil der Patienten ohne Unstimmigkeiten war mehr als dop-

	pelt so hoch in der post-Gruppe als in der prä-Gruppe (p-Wert siehe unten P2). Phase 3: Wurde nichts erwähnt
Sind die unterschiedlichen Ergebnisse nicht nur auf einen Zufall zurück zu führen?	Phase 1: p = 0.01 Phase 2: *p1*= 0.204 *p2*= 0.017 Phase 3: Keine Werte vorhanden
Wie präzise sind die Ergebnisse?	Das Konfidenzintervall wurde nicht erwähnt. Es lassen sich dementsprechend keine Schlüsse zur Präzision der Ergebnisse ziehen.
Anwendbarkeit	
Sind die Ergebnisse auf meine Patient/-innen übertragbar?	Phase 1: Da es sich um eine Simulation handelte, um das Tool in einem kleinen Rahmen zu testen, sind die Ergebnisse nur teilweise anwendbar auf unsere Fragestellung. Aber die Ergebnisse wurden dazu benutzt, um das Tool zu verbessern. Phase 2: Es ist im Akut- wie Langzeitsetting einfach anwendbar für ältere Patient/-innen. Es ist besonders geeignet, da diese meist über eine Medikationsliste mit vielen Medikamenten verfügen. Phase 3: Ja, da die Auswertung gezeigt hat, dass dieses Tool nützlich ist, wohl aber zeitgleich auch zeitintensiver ist.

Wurden alle für mich wichtigen Ergebnisse betrachtet?	Nein, die Langzeitbeurteilung fehlt aus unserer Sicht (z.B. nach 6 Monaten)
Ist der Nutzen die möglichen Risiken und Kosten wert?	Edukation nimmt anfangs mehr Zeit in Anspruch, jedoch kann durch diese Intervention höchstens positives und nichts negatives verursacht werden. Da aber in der Praxis keine signifikanten Resultate erreicht werden konnten, sind die Kosten und Risiken höher als der Nutzen.

- Die Zulassung durch eine Ethikkommission wurde nicht erwähnt.

Kritische Beurteilung Pitkälä et al. (2014)

- nach Behrens und Langer (2016)

Artikel:
Pitkälä, K. H., Juola, A.-L., Kautainen, H., Soini, H., Finne-Soveri, U. H., Bell, J. S., & Björkman, M. (2014). Education to Reduce Potentially Harmful Medication Use Among Residents of Assisted Living Facilities : A Randomized Controlled. Journal of the American Medical Directors Association, 15(12), 892–898. https://doi.org/10.1016/j.jamda.2014.04.002

Es handelt sich hierbei um eine RCT.

Glaubwürdigkeit	
Wie wurden die Teilnehmenden rekrutiert und den Untersuchungsgruppen zugeteilt?	Aus 36 Abteilungen wurden 7 ausgewählt, die in etwa gleich sind laut RAI Einschätzung -> insgesamt 20 Stationen. Diese 20 Stationen wurden in Zweiergruppen eingeteilt, die sich charakteristisch ähnlich waren. Anschliessend wurden durch einen Nummerngenerator die Stationen innerhalb dieser Zweiergruppe willkürlich in die KG und IG eingeteilt. Aus Gründen der Verwirrung wurden nicht TN randomisiert, sondern die Stationen. Die Study Nurses rekrutierten innerhalb dieser Stationen die TN anhand der Einschlusskriterien (<65J. alt, permanent in einem Pflegeheim wohnend, Finnisch sprechend, mind. 1 Medikament, <6Mt. Lebenserwartung, schriftl. Einwilligung durch TN o. gesetzlicher Vertreter).
Wie viele Patient/-innen, die anfangs in die Studie aufgenommen wurden, waren am Ende noch dabei?	Anfangs waren es 227 TN, davon waren am Ende der Studie noch 189 TN dabei. Nach 6Mt. Waren es 41 TN weniger (Ausfallrate von 18.1%) und nach 12Mt. Waren es 63 TN weniger (Ausfallrate von 27.8%). Dies aufgrund Exitus (von 63TN waren davon 39 in der IG und 24 in der KG).
Waren die Teilnehmenden, das Personal und die Untersuchenden verblindet?	Die Untersucher und die Teilnehmer waren verblindet. Ob das Personal verblindet war, ist aus dem Artikel heraus nicht ersichtlich. Es wäre sicherlich

	möglich gewesen, dies zu tun.
Waren die Untersuchungsgruppen zu Beginn der Studie ähnlich?	Ein signifikanter Unterschied zwischen den beiden Gruppen bestand in folgenden Charakteristika: - weibliches Geschlecht (p=0.05) - Charlson's Comorbidity index (p<0.004) - Gesundheitsbezogene Lebensqualität (p= 0.002) - Anzahl Medikament (p=0.007) - Anzahl schädigender Medikamente, «Brauchende» (p=0.038)
Wurden die Untersuchungsgruppen – abgesehen von der Intervention – gleich behandelt?	Ja, wurden sie.
Wurden alle Teilnehmenden in der per Randomisierung zugeteilten Gruppe bewertet?	Nein. Beim sechs monatigen Follow-up konnten bei drei TN keine Daten gesammelt werden (1TN aus der IG und zwei TN aus der KG).
War die Grösse der Stichprobe ausreichend gewählt, um einen Effekt nachweisen zu können?	Ja, ein Power von 80% wurde berechnet und eingehalten (→ mind. 106 TN pro Gruppe).
Stehen die Ergebnisse im Einklang mit anderen Untersuchungen auf diesem Gebiet?	Eine RCT mit einer Edukationsintervention für die Pflege wurde bisher noch nicht durchgeführt. Jedoch zeigen andere Prä-Post-Studien, dass Edukation zur Reduzierung der Medikationsfehler beitragen kann.
Aussagekraft	
Wie ausgeprägt war der Behandlungseffekt?	Häufigkeit schädigender Medikamentennutzung: Die Häufigkeit schädigender Medikamentennutzung reduzierte sich signifikant nach 12Mt. um -11.7 in der IG. In der KG gab es mi +3.4 keine signifikanten Änderungen. Reduzierung der durchschnittlichen Anzahl an Medikamenten:

	Durch die Intervention konnte in der IG die durchschnittliche Anzahl an Medikamenten signifikant um -0.43 verringert werden, blieb in der KG jedoch stabil mit +0.11.
Sind die unterschiedlichen Ergebnisse nicht nur auf einen Zufall zurück zu führen?	Nein, sind nicht auf Zufälle rückführbar. Häufigkeit schädigender Medikamentennutzung: *p*=0.009 in IG *p*=0.34 in KG Betreffend der Häufigkeit von vorkommender schädigender Medikamentennutzung konnte eine signifikante Änderung zwischen IG und KG erbracht werden (*p*=0.022). Reduzierung der durchschnittlichen Anzahl an Medikamenten: *p*=0.0024 in IG *p*=0.27 in KG Die Differenz bei der durchschnittlichen Anzahl an an Medikamenten war zwischen IG und KG signifikant (*p*=0.0035).
Wie präzise sind die Ergebnisse?	Es wurde bei allen Berechnungen ein Konfidenzintervall von 95% gewählt. Die Ergebnisse sind präzise. Häufigkeit schädigender Medikamentennutzung: CI95% -20.5; -2.9 in IG CI95% -3.7; 10.6 in KG Reduzierung der durchschnittlichen Anzahl an Medikamenten: CI95% -0.15; -0.71 in IG CI95% -0.09; 3.1 in KG
Anwendbarkeit	

Sind die Ergebnisse auf meine Patient/-innen übertragbar?	Ja, Alter und Setting stimmt.
Wurden alle für mich wichtigen Ergebnisse betrachtet?	Ja.
Ist der Nutzen die möglichen Risiken und Kosten wert?	Ja, relativer kleiner Kostenpunkt mit grosser Wirkung. Mögliche Wiederholungen des Edukationsprozesses möglich.

- Zulassung durch die Ethikkommission des Helsinki University Central Hospital und die schriftlichen Teilnahmebestätigungen der Probanden, bzw. deren gesetzlicher Vertreter sind vorhanden.

Kritische Beurteilung Poon et al. (2010)

- nach Behrens und Langer (2016)

Artikel:
Poon, E. G., Keohane, C. A., Yoon, C. S., Ditmore, M., Bane, A., Levtzion-Korach, O., … Gandhi, T. K. (2010). Effect of Bar-Code Technology on the Safety of Medication Administration. New England Journal of Medicine, 362(18), 1698–1707. https://doi.org/10.1056/NEJMsa0907115

Es handelt sich hierbei um eine Prä-Post-Studie.

Glaubwürdigkeit	
Wie wurden die Teilnehmenden rekrutiert und den Untersuchungsgruppen zugeteilt?	Es waren 1'726 Teilnehmende an der Studie beteiligt. Die Teilnehmenden mussten zwischen Februar und Oktober 2005 im Untersuchungsspital stationär aufgenommen worden sein. Es wurde weder der genaue Rekrutierungsablauf noch die Zustimmung seitens der Teilnehmenden erwähnt. Als einziges Ausschlusskriterium galten Patient/-innen der Onkologie.
Wie viele Patient/-innen, die anfangs in die Studie aufgenommen wurden, waren am Ende noch dabei?	Nicht anwendbar, da es sich um eine prä-post Studie handelt.
Waren die Teilnehmenden, das Personal und die Untersuchenden verblindet?	Nein.
Waren die Untersuchungsgruppen zu Beginn der Studie ähnlich?	Ja, die Charakteristika zwischen der Gruppe vor der Intervention und der Gruppe nach der Intervention sind ähnlich. Es gibt jedoch einen signifikanten Unterschied betreffend die Anzahl an beobachteten Medikamentenabgaben und der Anzahl an Patient/-innen vor und nach der Intervention. Die Anzahl an beobachteten Medikamentenabgaben auf der medizinischen Abteilung war vor der Intervention (2008/6723) signifikant tiefer als nach der Intervention (2232/7318) ($p<0.001$). Zudem wa-

	ren signifikant mehr Patient/-innen nach der Intervention (939/1726) an der Studie beteiligt als vor der Intervention (787/1726) (p<0.001).
Wurden die Untersuchungsgruppen – abgesehen von der Intervention – gleich behandelt?	Nicht anwendbar, da es sich um eine prä-post Studie handelt.
Wurden alle Teilnehmenden in der per Randomisierung zugeteilten Gruppe bewertet?	Nicht anwendbar, da es sich um eine prä-post Studie handelt.
War die Grösse der Stichprobe ausreichend gewählt, um einen Effekt nachweisen zu können?	Die Power wurde nicht berechnet, die Anzahl der Teilnehmenden, bzw. der verabreichten Medikamente (n=14'041) scheint jedoch gross genug zu sein, um einen Effekt nachweisen zu können.
Stehen die Ergebnisse im Einklang mit anderen Untersuchungen auf diesem Gebiet?	Ja.
Aussagekraft	
Wie ausgeprägt war der Behandlungseffekt?	Nicht-zeitbedingte Medikamentenabgabefehler: Mit dem eMAR Barcode Scanning konnten die Medikamentenabgabefehler signifikant von 776 auf 495 reduziert werden. Dies entspricht einer relativen Risikoreduktion von 41.4%. Die Anzahl der möglichen unerwünschten Medikamentenwirkungen im Zusammenhang mit den nicht-zeitbedingten Medikamentenabgabefehlern sank signifikant von 213 (entspricht 3.1%) möglichen unerwünschten Medikamentenwirkungen ohne Verwendung eMAR Barcode Scanning, auf 114 (entspricht 1.6%). Dies entspricht eine Risikoreduktion von 50.8%.

	Die Anzahl der zeitbedingten Medikamentenabgabefehler fiel signifikant von 1'126 (entspricht 16.7%) auf 891 (entspricht 12.2%) mit dem eMAR Barcode Scanning. Dies entspricht einer relativen Risikoreduktion von 27.3%. Die Anzahl der möglichen unerwünschten Medikamentenwirkungen im Zusammenhang mit den zeitbedingten Medikamentenabgabefehlern verringerte sich nicht signifikant von 34 (entspricht 0.5%) ohne eMAR Barcode Scanning auf 30 (entspricht 0.4%) mit Barcode Scanning. Dies entspricht einer relativen Risikoreduktion von 18.9%.
Sind die unterschiedlichen Ergebnisse nicht nur auf einen Zufall zurück zu führen?	Die Ergebnisse sind nicht auf einen Zufall zurück zu führen. Reduktion der nicht-zeitbedingten Medikamentenabgabefehler: $p<0.001$ Reduktion der möglichen unerwünschten Medikamentenwirkungen (nicht-zeitbedingt): $p<0.001$ Reduktion der zeitbedingten Medikamentenabgabefehler: $p=0.001$ Reduktion der möglichen unerwünschten Medikamentenwirkungen (zeitbedingt): Keine signifikante Reduktion, $p=0.44$
Wie präzise sind die Ergebnisse?	Alle Ergebnisse sind präzise. Nicht-zeitbedingte Medikamentenabgabefehler: CI 95% -34.2; -47.6 Reduktion der möglichen unerwünschten Medikamentenwirkungen (nicht-zeitbedingt):

	CI 95% -39.1; -61.7 Zeitbedingte Medikamentenabgabefehler: CI 95% -21.0; -33.8 Reduktion der möglichen unerwünschten Medikamentenwirkungen (zeitbedingt): CI 95% -60.4; 25.5
Anwendbarkeit	
Sind die Ergebnisse auf meine PatientInnen übertragbar?	Teilweise, da die Studie nur im Spitalsetting durchgeführt wurde und nicht auch im Pflegeheimsetting. Zudem liegt der Altersdurchschnitt der Population wenig unter den angestrebten 64 Lebensjahren.
Wurden alle für mich wichtigen Ergebnisse betrachtet?	Ja.
Ist der Nutzen die möglichen Risiken und Kosten wert?	Ja. Falls die finanziellen Ressourcen zur Anschaffung eines solches Geräts vorhanden sind, empfehlen die Autorinnen den Barcode Scanner. Die positiven Effekte sind bewiesen.

- Die Zulassung durch eine Ethikkommission wurde nicht erwähnt.

Kritische Beurteilung van Welie et al. (2016)

- nach Behrens und Langer (2016)

Artikel:
van Welie, S., Wijma, L., Beerden, T., van Doormaal, J., & Taxis, K. (2016). Effect of warning symbols in combination with education on the frequency of erroneously crushing medication in nursing homes: An uncontrolled before and after study. BMJ Open, 6(8), 1–7. https://doi.org/10.1136/bmjopen-2016-012286

Es handelt sich hierbei um eine Prä-Post-Studie.

Glaubwürdigkeit	
Wie wurden die Teilnehmenden rekrutiert und den Untersuchungsgruppen zugeteilt?	Der Rekrutierungsprozess wurde nicht genannt. Die Untersuchungsgruppen ergaben sich durch den Zeitraum der Datenerhebung (November-Dezember 2013 prä-Gruppe, bzw. März 2014 post-Gruppe).
Wie viele Patient/-innen, die anfangs in die Studie aufgenommen wurden, waren am Ende noch dabei?	Nicht anwendbar, da es sich um eine prä-post Studie handelt.
Waren die Teilnehmer, das Personal und die Untersucher verblindet?	Die Teilnehmer waren verblindet, das Personal und die Untersucher nicht.
Waren die Untersuchungsgruppen zu Beginn der Studie ähnlich?	Ja, es gab keine signifikanten Unterschiede in den Charakteristika.
Wurden die Untersuchungsgruppen – abgesehen von der Intervention – gleich behandelt?	Nicht anwendbar, da es sich um eine prä-post Studie handelt.
Wurden alle Teilnehmenden in der per Randomisierung zugeteilten Gruppen bewertet?	Nicht anwendbar, da es sich um eine prä-post Studie handelt.
War die Grösse der Stichprobe ausreichend gewählt, um einen Effekt nachweisen	Ja, ein Power von 500 abgegebenen Medikamenten wurde berechnet. Präintervention waren es 681 ausgeteilte Medikamente ausgeteilt, post-

zu können?	Intervention waren es 636 verteilte Medikamente.
Stehen die Ergebnisse im Einklang mit anderen Untersuchungen auf diesem Gebiet?	Ja.
Aussagekraft	
Wie ausgeprägt war der Behandlungseffekt?	Anzahl an irrtümlich gemörserten Medikamenten: Die Anzahl an irrtümlich gemörserten Medikamenten konnte von 21 auf 3 signifikant reduziert werden (von 3.1% auf 0.5%). Dies entspricht einer relativen Risikoreduktion von 0.15. Anzahl an Patient/-innen mit gemörserten Medikamenten: Die Anzahl an Patient/-innen mit gemörserten Medikamenten reduzierte sich nicht signifikant von 19 vor der Intervention auf 11 nach der Intervention (von 11.6% auf 7,3%, p=0.20).
Sind die unterschiedlichen Ergebnisse nicht nur auf einen Zufall zurück zu führen?	Anzahl an irrtümlich gemörserten Medikamenten: Der p-Wert wurde nicht genannt, nur dass es signifikant war, was mit einem RR von 0.15 annehmbar ist. Anzahl an Patient/-innen mit gemörserten Medikamenten: *p*=0.20
Wie präzise sind die Ergebnisse?	Anzahl an irrtümlich gemörserten Medikamenten: Es wurde mit einem CI95% 0.05; 0.51 -> Ergebnisse sind präzise.
Anwendbarkeit	
Sind die Ergebnisse auf meine Patient/-innen übertragbar?	Teilweise anwendbar da die Studie nur in Pflegeheimen durchgeführt wurde.
Wurden alle für mich wichtigen Ergebnisse betrachtet?	Die Langzeitwirkung der Intervention wurde aus Sicht der Autorinnen zu wenig beachtet.

Ist der Nutzen die möglichen Risiken und Kosten wert?	Ja, mit relativ geringem Aufwand und Kosten kann die Fehlerrate gesenkt werden – ohne Risiken.

- Die Studie wurde von keiner Ethikkommission überprüft. Eine Zulassung von offizieller Seite her wurde im Artikel nicht erwähnt.

ANHANG E: BEERS-LISTE

Es folgt eine adaptierte Beers-Liste von Schwalbe et al. (2007). Diese Liste wurde von ihnen übersetzt und an das Deutsche Gesundheitswesen angepasst.

Übersetzte und adaptierte Beers-Liste für potenziell ungeeignete Arzneimittel bei älteren Patienten. Liste 1 – Liste potenziell ungeeigneter Arzneimittel, unabhängig von Krankheit (UAW = unerwünschte Arzneimittelwirkung, ZNS = zentrales Nervensystem); [1]++ = hohe Relevanz, + = niedrigere Relevanz; [2] Symptome wie Mundtrockenheit, Miktionsprobleme, verminderte Schweißsekretion, Reizleitungsstörungen

Arzneistoff bzw. Arzneistoffklasse (Handelsname [Beispiel])	Bedenken bei älteren Patienten: 1. Verträglichkeitsprobleme 2. Wirksamkeitsprobleme → Empfehlungen	Bewertung[1]
Amiodaron (Cordarex®)	1. Herzrhythmusstörungen (QT-Zeit-Verlängerung) 2. Wirksamkeit ungewiss	++
Antidepressiva, trizyklische: Amitriptylin (Saroten®), Doxepin (Aponal®), Imipramin (Tofranil®)	Starke anticholinerge[2] und sedierende Wirkungen → Selten Antidepressiva der 1. Wahl	++
Anticholinergika, Antihistaminika: Azelastin (Allergodil®), Clemastin (Tavegil®), Cyproheptadin (Peritol®), Dexchlorpheniramin (Polaronil®), Dimetindenmaleat (Fenistil®), Diphenhydramin (Sedopretten®), Doxylaminsuccinat (Mereprine®), Ebastin (Ebastel), Hydroxyzin (Atarax®), Ketotifen (Zaditen®), Mequitazin (metaplexan®), Mizolastin (Mizollen®), Promethazin (Atosil®)	1. Erhöhte Empfindlichkeit → Neuere Antihistaminika (Cetirizin, Loratadin) ohne anticholinerge Wirkungen bevorzugen	++
Barbiturate (außer Phenobarbital), wenn nicht zur Behandlung einer Epilepsie	1. Hohes Abhängigkeitspotenzial, stark sedierend → Besser verträgliche Sedativa/Hypnotika einsetzen (z.B. kurzwirksame Benzodiazepine, s.dort)	++
Benzodiazepine, kurzwirksame (höhere Dosen): >3 mg Lorazepam (Tavor®), >60 mg Oxazepam (Adumbran®), >2 mg Alprazolam (Xanax®), >15 mg Temazepam (Planum®)	2. Erhöhte Empfindlichkeit → Dosisreduktion	++
Benzodiazepine, langwirksame: Chlordiazepoxid (Librium®), Clobazam (Frisium®), Clonazepam (Rivotril®), Dikaliumclorazepat (Tranxilium®), Diazepam (Valium®), Flunitrazepam (Rohypnol®), Flurazepam (Dalmadorm®), Medazepam (Rudotel®), Nitrazepam (imeson®), Prazepam (Demetrin®), Tetrazepam (Musaril®)	1. Häufig Halbwertszeiten von mehreren Tagen, dadurch erhöhte Gefahr von Stürzen → Mittel- oder kurzwirksame Benzodiazepine bevorzugen	++
Cimetidin (Tagamet®)	1. Unerwünschte ZNS-Arzneimittelwirkungen einschließlich Verwirrtheitszustände	+
Clonidin (Catapresan®)	1. Orthostatische Hypotension, unerwünschte ZNS-Arzneimittelwirkungen	+
Cyclandelat (Natil®)	2. Wirksamkeit ungewiss	+
Darmspasmolytika: Butylscopolaminiumbromid (Buscopan®), Belladonna-Alkaloide (Belladonnysat® Bürger)	1. Starke anticholinerge Wirkungen[2] 2. Wirksamkeit ungewiss → vermeiden, gerade zur längerfristigen Therapie	++
Digoxin (z. B. Lanicor®) in Dosen >0,125 mg/d (außer zur Behandlung von Vorhofarrhythmien)	1. Bei eingeschränkter Nierenfunktion: Herzrhythmusstörungen, gestörtes Farbsehen, Übelkeit, Verwirrtheitszustände, Halluzinationen	+
Diphenhydramin (Emesan®, Sedopretten®)	1. Verwirrtheitszustände, Sedierung → Nicht als Hypnotikum einsetzen; zur Notfallbehandlung allergischer Reaktionen: kleinstmögliche Dosis	++
Doxazosin (Cardular®)	1. Hypotension, Mundtrockenheit, Miktionsprobleme	+
Eisen(II)-Salze, in Dosen >325 mg/d (Ferrum Verla®)	1. Obstipation	+
Ergotamin und -derivate (Ergo-Kranit® Migräne)	2. Wirksamkeit ungewiss	+
Estrogene, orale Monopräparate (Estronorm®)	1. Karzinogenes Potenzial	+
Fluoxetin (Fluctin®), tägliche Einnahme	1. Exzessive ZNS-Stimulation, Schlafstörungen, Agitiertheit	++
Indometacin (Indometacin Sandoz®)	1. Höchste Rate an unerwünschten ZNS-Arzneimittelwirkungen von allen nichtsteroidalen Antiphlogistika (NSAR)	++
Laxanzien, stimulierende, über längeren Zeitraum: Aloe (Kräuterlax®), Bisacodyl (Dulcolax®), Natriumpicosulfat (Regulax®), Sennesblätter (Neda Früchtewürfel), Cascararinde (Legapas®)	1. Darmfunktionsstörungen	++
Methyldopa (Dopegyt®)	1. Bradykardie, Depression	++
Muskelrelaxanzien und Spasmolytika: Methocarbamol (Ortoton®), unretardierte Oxybutynin-Präparate (Oxybutynin HEXAL)	1. Starke anticholinerge[2] und sedierende Wirkungen, Schwächegefühl 2. Wirksamkeit in tolerierbaren Dosen ungewiss	++
Nichtsteroidale Antiphlogistika (NSAR) mit längerer Halbwertszeit in voller Dosierung über längeren Zeitraum: Naproxen (Naproxen beta), Piroxicam (Felden®)	1. Magen-Darm-Blutungen, Nierenversagen, Hypertonie, Herzinsuffizienz	++

Liste 1. (Fortsetzung)

Arzneistoff bzw. Arzneistoffklasse (Handelsname [Beispiel])	Bedenken bei älteren Patienten: 1. Verträglichkeitsprobleme 2. Wirksamkeitsprobleme → Empfehlungen	Bewertung[1]
Nifedipin, kurzwirkendes (Adalat®)	1. Hypotension, Obstipation	++
Nitrofurantoin (Nifuretten®)	1. Niereninsuffizienz	++
Orphenadrin (Norflex®)	1. Starke Sedierung, starke anticholinerge Wirkungen[2]	++
Reserpin (Briserin® N) in Dosen > 0,25 mg	1. Depression, Impotenz, Sedierung, orthostatische Hypotension	+
Thioridazin (Thioridazin-neuraxpharm®)	1. Sehr häufig ZNS- und extrapyramidale unerwünschte Wirkungen	++
Ticlopidin (Ticlopidin HEXAL®)	1. Agranulozytose 2. Nicht Acetylsalicysäure überlegen → Besser verträgliche Thrombozytenaggregationshemmer verfügbar (Clopidogrel/Plavix®)	++
ZNS-Stimulanzien: Cathin (Antiadipositum X 112 T®), Phenylpropanolamin (Boxogetten® S-vencipon), Amfepramon (Regenon®), Methylphenidat (Ritalin®)	1. Abhängigkeitspotenzial; Hypertonie, Angina pectoris, Myokardinfarkt	++

Übersetzte und adaptierte Beers-Liste für potenziell ungeeignete Arzneimittel bei älteren Patienten.
Liste 2 – Liste potenziell ungeeigneter Arzneimittel, in Abhängigkeit von Krankheiten

Krankheit	Arzneistoff bzw. *Arzneistoffklasse** (Handelsname [Beispiel])	Bedenken bei älteren Patienten	Bewertung[1]
Adipositas	*Atypisches Neuroleptikum:* Olanzapin (Zyprexa®)	Appetitstimulation, weitere Gewichtszunahme	+
Appetitlosigkeit und Unterernährung	*ZNS-Stimulanzien;* *Selektive Serotonin-Wiederaufnahmehemmer (SSRI):* Fluoxetin (Fluctin®)	Appetithemmung	++
Blutgerinnungsstörungen oder Therapie mit Antikoagulanzien	*NSAR,* Acetylsalicylsäure; *Thrombozytenfunktionshemmer:* Dipyridamol (Aggrenox®), Ticlopidin (Ticlyd®), Clopidogrel (Plavix®)	Erhöhung der Gerinnungszeit, erhöhter INR-Wert, gehemmte Thrombozytenaggregation mit erhöhtem Blutungsrisiko	++
Bluthochdruck	*ZNS-Stimulanzien*	Erhöhung des Blutdrucks	++
Obstipation, chronische	*Calciumkanalblocker; Anticholinergika; trizyklische Antidepressiva*	Verstärkung der Obstipation	+
COPD	*Langwirksame Benzodiazepine;* *Betablocker:* Propranolol (Obsidan®)	Unerwünschte ZNS-Arzneimittelwirkungen, Atemdepression, Verschlechterung von bestehender Atemdepression	++
Depression	Langzeitanwendung von *Benzodiazepinen;* *Sympatholytika:* Methyldopa (Presinol®), Reserpin (Briserin® N)	Verschlechterung der Depression oder Auslösen einer depressiven Episode	++
Epilepsie	*Neuroleptika:* Clozapin (Leponex®), Chlorpromazin (Propafenin®), Thioridazin (Melleril®); *Selektiver Noradrenalin/Dopamin-Wiederaufnahmehemmer:* Bupropion (Zyban®)	Verringerte Krampfschwelle	++
Blasenentleerungsstörungen (z. B. bei benigner Prostatahyperplasie)	*Anticholinergika, Antihistaminika; Antidepressiva; Laxanzien;* *Spasmolytika:* Tolterodin (Detrusitol®); *Muskelrelaxanzien:* Oxybutynin (Oxybutynin HEXAL®), Flavoxat (Spasuret®)	Verminderung des Urinflusses bis zum Harnverhalt	++
Herzrhythmusstörungen	*Trizyklische Antidepressiva*	Proarrythmogenes Potenzial (Veränderung des QT-Intervalls)	++
Herzinsuffizienz	*Arzneimittel mit hohem Natriumgehalt:* Alginate, Bicarbonate, Bisphosphonate, Citrate, Phosphate, Salicylate, Sulfate	Negativ inotrope Wirkung, mögliche Wasserretention, Verschlechterung der Herzinsuffizienz	++
SIADH/ Hyponatriämie	*Selektive Serotonin-Wiederaufnahmehemmer (SSRI):* Fluoxetin (Fluctin®), Citalopram (Cipramil®), Fluvoxamin (Fevarin®), Paroxetin (Seroxat®), Sertralin (Zoloft®)	Verschlechterung der Hyponatriämie	+
Kognitive Störungen	*Barbiturate; Anticholinergika; Spasmolytika; Muskelrelaxanzien; ZNS-Stimulanzien*	Verschlechterung der Kognition	++
Magen-/Darmulzera	*NSAR* (außer *Coxibe*), Acetylsalicylsäure (>325 mg)	Verschlechterung bestehender Ulzera, Entstehen zusätzlicher Ulzera	++
Parkinson-Krankheit	*Dopaminantagonisten:* Metoclopramid (MCP-ratiopharm®); *Typische Neuroleptika:* Chlorpromazin (Propaphenin®), Thioridazin (Melleril®)	Antidopaminerge und anticholinerge Wirkung[2]	++
Ohnmacht und Stürze	*Benzodiazepine; trizyklische Antidepressiva*	Störung der Koordination von Bewegungsabläufen; erhöhte Ohnmachts- und Sturzgefahr	++
Schlafstörungen	*Laxanzien; ZNS-Stimulanzien;* Bronchospasmolytikum: Theophyllin (Euphylong®); *MAO-Hemmer:* Moclobemid (Aurorix®), Tranylcypromin (Jatrosom N®);	ZNS-stimulierender Effekt	++
Stressinkontinenz	*Anticholinergika; langwirksame Benzodiazepine; trizyklische Antidepressiva;* *Alpha-Blocker:* Doxazosin (Cardular®), Prazosin (Minipress®), Terazosin (Heitrin®);	Polyurie, Verschlechterung der Inkontinenz	++

[1] ++ = hohe Relevanz, + = niedrigere Relevanz; [2] Symptome wie Mundtrockenheit, Miktionsprobleme, verminderte Schweißsekretion, Reizleitungsstörungen
NSAR = nichtsteroidale Antiphlogistika, COPD = chronisch obstruktive Lungenerkrankung, SIADH = Syndrom der inadäquaten ADH-Sekretion,
* = Arzneistoffbeispiele siehe Liste 1

ANHANG F: EINGESCHLOSSENE STUDIEN

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CLINICAL TRIAL

Nurse-led medication reviews and the quality of drug treatment of elderly hospitalized patients

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Abstract
Purpose To evaluate if nurses after receiving training in clinical pharmacology can improve the quality of the drug therapy in elderly hospitalized patients.
Methods Nurses were given a 1-day training in clinical pharmacology to identify drug-related problems (DRPs). All patients admitted to the ward aged 65 or more were studied. Patients at the same ward before the intervention were considered as control group. Outcome variables were re-hospitalized 3 months from discharge, drug-related re-admissions, the proportion of inappropriate drug use (IDU), and DRPs found by the nurses.
Results Of 460 patients (250 intervention group and 210 in the control group) 38 and 36%, respectively, had at least one re-admission to hospital (p=0.86) and 24% of the patients died. Eighteen and 17% (43/37), respectively, used one or more inappropriate drug (p 0.90). The nurses found 86 clinically significant DRPs not detected by the usual care. A substantial part of the DRPs detected by the nurses were revealed with assistance of Symptoms Assessment Form (SYM). There were no statistical difference in the number of drug-related re-admissions between the groups, 14/16, respectively, (p=0.40).
Conclusions Nurses are able to detect a high proportion of clinically relevant DRPs not detected by the usual care and thereby increase the quality of the drug treatment in elderly hospitalized patients. Our study showed no effect on re-hospitalization or IDU. By using a SYM nurses can find DRPs that computer-based decision support systems miss.

Keywords Drug-related problems · Nurse · Intervention · Symptoms assessment form · Inappropriate drug use (IDU)

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Introduction

Whenever a patient is treated with one drug or more, drug-related problems (DRPs) may occur. It may be a trivial DRP, not affecting the health outcome of the patient, or it could turn into a problem of clinical relevance, leading to hospitalization and/or death. People aged 65 and over have a higher prevalence of DRPs [1–3]. This may be due to a combination of factors such as several illnesses leading to a need for more drugs. Polypharmacy increases the risk of drug-drug interactions (DDIs) and other DRPs [4, 5]. Increased disability and dependency on assistance may result in difficulty adhering to the drug regime. Changes in age-related pharmacokinetics and pharmacodynamics may have an effect. The main reason for age-related effects on the drug action is that the drug elimination is less efficient in elderly people, so that drugs often produce greater and more long-lasting effects. The elimination rate is impaired as a result of age-related changes in the renal structure. Glomerular filtration rate (GFR) starts to decline from the age of 20 and will have fallen by about 50% at 75 years of age [6]. A considerable number of elderly patients with decreased renal function are being prescribed drugs that should be dose adjusted, used with caution, or avoided [7–9].

Many elderly people use potentially inappropriate medication [3, 8, 10–13]. Inappropriate drugs in older

people are drugs with no clear evidence-based indication. Drugs carry a substantially higher risk of adverse side-effects in the elderly compared to young people [14, 15].

A recently published study states that prescription of inappropriate medication to elderly people is highly prevalent, ranging from 12 to 40% in community-dwelling elderly and nursing home residents, respectively [11]. The quality of the drug therapy was evaluated in a study among elderly nursing home residents in Sweden, and the result showed that over 70% of the residents used one or more inappropriate drugs or drug combinations [13]. Other Swedish population-based studies among people 75 years and older have shown that inappropriate drug use (IDU) is common, with a prevalence of 16.5–19% [8, 12]. IDU is associated with adverse drug events (ADEs) and is an important reason for unplanned admittance to hospital of elderly people [8, 16–19]. The proportion of drug-related hospital admissions has been shown to be up to 6%, with a substantially higher proportion among elderly patients [2, 17, 18, 20–22]. This problem is well known and has been addressed in many studies. However, there is little agreement on how to prevent the need for drug-related hospital admission of elderly people. Regular reviewing of the medication treatment seems to be rational. Medication reviews have been made by pharmacists and by clinical pharmacologists [23–26], but the effects on the quality of the drug therapy or on the number of hospital admissions are contradictory.

Studies have shown that nurse-led medication reviews with subsequent intervention can reduce re-admissions to hospital of patients with heart failure [27, 28], and a home-based intervention assessed by a pharmacist and a nurse showed a 25% reduction in unplanned re-admissions to hospital [29, 30]. A recently published study has shown that after training in clinical pharmacology, nurses are able to identify DRPs not detected during the usual care in hospitalized patients [31]. There are, to our knowledge, no randomized studies aiming at reducing drug-related re-admission of elderly patients that evaluate the nurse's role in identifying potential DRPs.

Aim

The aim of this study was to evaluate if nurses, after specific training in clinical pharmacology, can improve the quality of the drug therapy in elderly hospitalized patients.

Materials and methods

Study site

This intervention study was carried out in a 22-bed ward of the Division of Internal Medicine in a large hospital in Stockholm. The ward admits approximately 1,750 patients a year, and 36 nurses serve on a regular basis in three shifts.

The patients

All patients aged 65 or more treated over a 3-month period (October–December 2006) at the ward represent the intervention group and were eligible for the study. Exclusion criterion was protected identity. Patients treated over a 3-month period (July–September 2006) at the same ward before the intervention were considered as control group.

The intervention

All nurses serving at the ward on a regular basis were offered a 1-day training in clinical pharmacology, described elsewhere [31]. Ninety percent (n=32) of the nurses participated. The purpose of the training was to give the nurses the knowledge and tools to identify patients at high risk of drug-related problems (DRPs) and to find the DRPs. Tools to find possible DRPs were a symptom assessment form (SYM) containing questions on symptoms caused by common drugs, access to a web application to estimate renal function by calculating creatinine clearance, and access to a special web application, the Janus Web Application (JWA) [32], to determine possible drug-drug interactions (DDIs). Two nurses were chosen to function as instructors for the other nurses. The instructors were each allowed 8 h/week for identifying possible DRPs in the patients admitted to the ward studied.

Outcome variables

Main outcome was re-hospitalization within 3 months from discharge. Secondary outcome was the proportion of inappropriate drug use (IDU) at discharge, the proportion of drug-related re-admissions, and the frequency of DRPs found by the nurses. Re-admission and death were examined for all studied patients within 3 months after discharge. Hospital admission data were provided by Hospital Episode Statistics. Determination of potential IDU is based on four quality indicators developed by The Swedish National Board of Health and Welfare [33]: use of at least one anticholinergic drug, use of at least one long-acting benzodiazepine (e.g., diazepam, flunitrazepam, nitrazepam), concurrent use of three or more psychotropic drugs (i.e., neuroleptics, anxiolytics, hypnotics/sedatives, antidepressants), and at least one combination of drugs that may lead to a potentially serious DDI type D. IDU is defined as exposure to at least one of the four quality indicators. These quality indicators are in accordance with the Beers

criteria [14, 33]. Serious DDIs are classified according to the JWA for detecting DDIs [32]. In brief, DDIs are divided into four levels of clinical relevance, types A, B, C, and D [32]. We have focused on potentially serious DDIs type D, "should be avoided."

Drug-related re-admission

Drug-related morbidity is defined as admission to hospital for treatment of drug-related adverse effects according to the International Classification of Diseases 9th version (ICD-9) (WHO 1978). Six diagnostic codes were used: X579 (accidental exposure to other and unspecified factors), X6199 (intentional self-poisoning by and exposure to antiepileptic, sedative-hypnotic, antiparkinsonian, or psychotropic drugs, not elsewhere classified), X4403 (accidental poisoning by and exposure to other and unspecified drugs, medicaments, and biological substances), Y579 (complications of drug or medicament, unspecified) F130 (mental and behavioral disorders due to use of sedatives or hypnotics), and X403 (accidental poisoning by and exposure to non-opioid analgesics, antipyretics, and antirheumatics). Drug-related re-admission was also estimated by a reviewer who scrutinized the patient's medical record. Drug-related re-admission was defined if the patient's medical record included any of these diagnostic codes at re-admission or if the reviewer who scrutinized the medical records judged the re-admission to be drug-related. Drug-related causes for re-admission were assessed as "major cause for the re-admission" or "contributing cause for the re-admission," and as to whether or not the assessment was "certain" or "uncertain."

Statistics

Power calculation was made for the second outcome variable, IDU. A sample of 396 patients (198 per group) was needed in order to detect with 80% power a difference of 40% (from 30% to 18%) in the number of patients with one or more inappropriate drug or drug combination. A P value of <0.05 was considered significant.

Statistical Package for the Social Sciences (SPSS) version 16.0 was used for the analyses.

Statistical significance was assessed with an alpha level of 0.05. Basic chi-squared and t-tests were performed to examine the difference between the intervention and control groups.

Ethics approval

Approval was obtained from the Research Ethics Committee, Karolinska Institutet, Stockholm, Sweden.

Results

The nurses found 86 clinically significant DRPs not detected by the usual care. There was no statistically significant difference in re-admission in the intervention or control group. There was also no statistically significant difference in the number of patients using inappropriate drugs.

Patient characteristics

Table 1 shows the characteristics of the 460 patients enrolled in the study—250 in the intervention group and 210 in the control group. There were 56% women in the intervention group and 53% in the control group. The mean age of the patients was 80.3 years. Drugs were used on a regular or as-needed basis by 94% (n=433) of the study population. The mean number of different drugs per person used on a regular or as-needed basis at admission was 6.9 and 6.2, respectively, in the two groups (range 0–20). More than half of the patients had some degree of renal insufficiency, and the proportion of patients having serum creatinine levels within the normal range but reduced estimated GFR ("hidden renal insufficiency") was 82 with

Table 1 Baseline characteristics (n=460)

	Intervention		Control	
	Male (n=109)	Female (n=141)	Male (n=99)	Female (n=111)
Age, mean	78.7	82.2	78.2	82.1
Number of drugs at admission, mean	6.9	6.9	5.8	6.6
Renal insufficiency count[a]	56/103 (54%)	80/140 (57%)	54/97 (56%)	63/108 (58%)
Hidden renal insufficiency, count[b]	14/74 (19%)	34/83 (41%)	12/59 (20%)	22/61 (36%)

[a] Seven in the intervention group and five in the control group could not have their renal function estimated due to lack of creatinine value

[b] Ninety-three in the intervention group and 90 in the control group could not have their renal function estimated due to lack of creatinine value or weight data

a substantially higher proportion among the women than men, 56/144 (39%) and 26/133 (20%), respectively, in thos in which creatinine clearance could be estimated. There were no apparent differences in the demographic profiles of the intervention and the control group.

Re-admission to hospital

There was no statistically significant difference in re-admission between the groups (Table 2). During follow-up (3 months after discharge), 37% (n=170) of the 460 patients had had at least one re-admission to hospital, 38% (n=94) and 36% (n=76), respectively, in the two groups (P=0.86). During the 3-month follow up, 24% of the patients died. The combined rate of re-admission and death was 59% (n=147) in the intervention group, and 54% (n=115) in the control group (P=0.64).

The prevalence of inappropriate drug use (IDU) at discharge

Table 2 shows the distribution of IDU. The overall prevalence of patients using one or more inappropriate drugs was 17%. There were 43 patients using one or more inappropriate drugs in the intervention group and 37 patients in the control group, i.e., no significant difference between the groups (P=0.90). Some of the patients used more than one inappropriate drug. The overall prevalence of IDU was 102 (60 intervention/42 control). Anticholinergics accounted for 40% (n=24/17), long-acting benzodiazepines for 17% (n=9/8), three or more psychotropic drugs for 32% (n=22/11), and potentially serious drug-drug interactions (grade D) counted for 11% (n=5/6). The most frequently prescribed anticholinergic drugs were urological spasmolytics (G04BD) in the intervention group, and opiates and opioids in combination with spasmolytics (N02AG) in the control group. The most common potentially serious drug-drug interaction was a combination of potassium supplement and potassium-sparing diuretic.

DRPs detected by the nurses

Of the 250 patients in the intervention group, medication reviews were documented for a total of 73 patients. The rest, 177 patients, received the usual care, but by nurses who had had the special pharmacological training and who were encouraged to be alert for any signs of DRPs. The nurses found 86 DRPs in 53 patients not detected by the usual care (Table 3). The nurses revealed patients at risk of adverse drug reactions (ADRs) due to a combination of decreased renal function and too high a dosage of drugs, or inappropriate drugs due to the patient's age. The nurses also found potential DDIs (types C and D), such as risk of intestinal bleeding due to a combination of antitrombotic agents and NSAIDs; risk of nil effect of antibiotics due to a DDI between ciprofloxacin and iron compounds or calcium compounds; and risk of hyperkalemia due to a DDI between potassium chloride and potassium-sparing diuretics. The DDIs in the current study had not caused any symptoms for the patient. Furthermore, 23 (ADRs) according to the WHO definition [34] were detected by the nurses. The

Table 2 Inappropriate drug use (IDU)

	Intervention (n=250)		Control (n=210)		P[a]
	Male (n=109) (%)	Female (n=141) (%)	Male (n=99) (%)	Female (n=111) (%)	
DRPs detected by the nurses	31	55			
Re-admissions	48 (44)	46 (33)	38 (38)	38 (34)	0.86
Patients with one or more inappropriate drugs or combinations of drugs	23 (21)	20 (14)	11 (11)	26 (23)	0.90
Inappropriate drugs used	32	28	11	31	
Anticholinergic drugs	12	12	5	12	0.51
Long-acting benzodiazepines	3	6	0	8	1.0
Three or more psychotropic drugs	12	10	4	7	0.15
Potential DDI type D	5	0	2	4	0.56
Number of drugs at discharge, mean	8.0	8.1	6.9	7.8	0.12
Withdrawn drugs, mean	0.9	1.0	0.9	0.6	0.16
Days of hospitalization, mean	6.1	5.2	4.5	4.8	0.04
Death within 3 months, count	32 (29)	28 (20)	29 (29)	20 (18)	0.91

[a] P values for men and women together

Table 3 Drug-related problems detected by nurses (n=86)

Drug-related problem	Number
Risk of ADR	34
Potential DDI	25
ADR	23
Other	3
No clear indication	1

detected ADRs are presented in Table 4. A substantial number of the DRPs were revealed with assistance of SYM.

Assessment of the drug-related causes for re-admission

There was no difference in the number of drug-related re-admissions between the groups. Of the 170 patients who were re-admitted to hospital, 105 records were available for analysis of possible drug-related causes for the re-admission. Of these re-admissions, 28% were judged to be drug-related (14 patients in the intervention group and 16 in the control group, with no statistical difference, P=0.40).

Discussion

This study is the largest of its kind of nurse-led intervention aiming at reducing DRPs. The study shows that a 1-day training of nurses in clinical pharmacology contributes to their finding patients at risk of getting a DRP, enabling the nurses to prevent an ADR. The nurses in this study found 86 clinically significant DRPs not detected by the usual care. Although there was no decrease in re-admissions after the intervention, we can show that many DRPs not detected by the usual care could easily be detected by nurses. This nurse-led intervention is new and has been tested in a previous study [31]. The new feature of this method is the structure whereby the nurse has a leading role. Three measures are undertaken: completion of an SYM containing questions on symptoms caused by common drugs, measurement of the patient's actual renal function, and determination of possible DDIs.

Other studies

The literature on nurse-led intervention aiming at reducing DRPs and IDU is limited. A meta-analysis from 2006 shows no evidence for the effectiveness of nurse-led intervention aiming at reducing re-admission to hospital and drug-related morbidity [18]. In contrast, Blue et al. were able to demonstrate that nurses could improve the outcome of patients admitted to hospital with heart failure. Compared with the usual care, the patients in the intervention group had fewer re-admissions and spent fewer days in hospital because of heart failure [27]. A Dutch study also indicated that a combined intervention by a clinician and a cardiovascular nurse substantially reduced hospitalization for worsening heart failure and/or all-cause mortality [28].

Pharmacist-led interventions aiming at reducing DRPs are quite common but without consistent evidence of their value at reducing re-admissions. Recently two meta-analyses have been published showing that pharmacists failed to reduce hospital admissions [18, 24]. However, a slight reduction in the number of prescribed drugs could be showed. The authors even showed a higher rate of hospital admissions after intervention by a pharmacist, which shows the complexity of the problem [24]. However, intervention studies made by nurses and pharmacists or nurses and clinical pharmacologists working together in multi-disciplinary teams have shown some benefits [25, 26, 30]. In summary, previous studies of interventions aiming at reducing DRPs are inconsistent. The complexity of the problem of drug-related hospital admissions requires a new approach.

Table 4 Adverse drug reactions detected by the nurses (n=23)

Symptom	Number	Involved drug
Dry mouth	4	Diuretics
Nausea	4	Analgesics, antibiotics
Constipation	3	Analgesics, iron compounds
Muscle pain	2	Lipid-modifying agents
Restless legs	1	Hypnotics
Dizziness	1	Hypnotics
Hangover	1	Hypnotics
Diarrhea	1	Antibiotics
Hypotension	1	Angiotensin-converting enzyme (ACE) inhibitor
Nightmare	1	Betablockers
Confusion	3	Analgesics, antipsychotic agents (risperidon)
Itch	1	Anastrozole

In accordance with other studies, our study describes the proportion of inappropriate drugs used in the treatment of elderly people as high [3, 8, 10, 12, 13, 26]; 17% of our study population took one or more inappropriate drugs or drug combinations. However, some drugs routinely considered to be inappropriate may be appropriate for the individual patient within the clinical context [35]. There may be a risk of overestimating the use of inappropriate drugs when using computer-based decision support systems (CDSS). A medication review must always include a clinical judgement by a physician with knowledge of the patient's present health and social status. A substantial part of the DRPs found by the nurses were of a kind that could not have been detected with a CDSS. To be able to find these DRPs, a symptom assessment made by a nurse was needed.

Renal function

A major portion of the DRPs found by the nurses were patients at risk of getting ADRs due to impaired renal function. To avoid IDU in the elderly, an accurate assessment of the renal function is extremely important [36, 37]. Although serum creatinine is the most common laboratory test used for identifying renal impairment, it fails to detect such in many patients, particularly elderly women [36–39]. In our study, 54% of the patients had some degree of renal insufficiency, and the prevalence of "hidden renal insufficiency" (serum creatinine levels within the normal range but reduced estimated GFR) was high, especially among the women (Table 1). Our findings that women are more likely to have a "hidden renal insufficiency" is in agreement with findings in other studies [37, 38]. In our study, 39% of the women and 20% of the men (of 144 women and 133 men in whom creatinine clearance could be estimated) suffered from "hidden renal insufficiency," which increases the risk of getting too high drug doses. Medication safety can potentially be improved through a more comprehensive assessment of the renal function. Calculation of an estimated creatinine clearance is easily and quickly done and could be part of a routine assessment by a nurse to identify patients at risk of having DRPs [37]. Other routines are already implemented to identify at-risk patients, e.g., calculation of body mass index (BMI) to identify patients at risk of malnutrition, and calculation of risk of pressure ulcers by using the modified Norton scale.

Interpretations

One possible reason for the results may be that the outcome re-hospitalization, and the prevalence of patients with IDU, may not relate to the intervention delivered. The mortality within 3 months in this study was 24%, which indicates how frail these patients are. The goal of caring for this vulnerable population must be to optimize their quality of life. Many of the DRPs found were causing the patients ADRs that are known to severely affect the patients' quality of life, such as dry mouth, constipation, and nausea [40–44].

However, previous studies have shown that even a short instruction and training of nurses can result in nurses detecting DRPs and reporting ADRs [31, 45, 46]. Drug treatment of elderly people presents a complex problem that requires an interdisciplinary approach. Nurses often are the first to notify the physician of the need for a medication or medication changes. Nurses work near the patient and have a comprehensive view of him/her and are thus in a perfect position to identify and alert for possible DRPs.

Limitations and strengths

This study required no consent by the patients, so all patients 65 and older admitted to the ward during the study period were included, and there was thus no selection bias. The intervention and the control groups were essentially equal in characteristics. None of the patients was withdrawn or lost to follow-up. Hospital admission data were provided by data from the Hospital Episode Statistics and are thus unlikely to have introduced bias. The educational intervention and the method for DRP detection have been evaluated in another study, showing them to be feasible and well accepted by nurses [31]. The ward has no history of seasonal variation. Educational interventions other than ours or changes among the personnel or in the ward were outside our control, but there was no time gap between the control group (July–September 2006) and the intervention group (October–December 2006).

The 3-month cut-off point was selected to capture the majority of re-admitted patients. In previous studies we established that almost 40% of all patients admitted to an internal medicine ward are re-admitted within 6 months after discharge, and 17% of the patients died [26, 31].

A reasonable reduction in re-admission would have been 5 percentage units, i.e., half of the drug-related hospital-admissions, since 10–30% of the hospitalization of the elderly is drug-related [1–3]. To test this difference statistically with an alpha of 0.05 and a beta of 80%, the study would have required at least 9,336 patients in each group. Such a study was not possible for us to do in this clinical setting. Although we had no power for the primary outcome, we wanted the outcome to be re-admission because of its indisputable value as indicator of health.

Since it was impossible for us to obtain power for our primary outcome, we chose to calculate power for our secondary outcome, IDU at discharge. IDU is a more subtle, flexible but disputable indicator for health. Some medications routinely considered to be inappropriate may be appropriate for the individual patient. In the current study, 17% of the patients were exposed to a potential IDU, which is in agreement with other Swedish population studies [12]. In our power calculation, we thought the prevalence would be higher because the patients in our study were admitted to hospital and thus more vulnerable and more exposed to poly-pharmacy [11].

Conclusions

Our study shows that nurses are able to detect a high proportion of clinically relevant DRPs not detected by the usual care, thereby increasing the quality of the drug treatment in elderly hospitalized patients. Our study showed no effect on re-hospitalization or IDU. By using a symptoms assessment form, nurses can find DRPs that computer-based decision support systems (CDSS) and usual care miss.

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Reduction of Inappropriate Medications among Older Nursing-Home Residents

A Nurse-Led, Pre/Post-Design, Intervention Study

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Abstract

Background: Medication-related problems are common in the growing population of older adults and inappropriate prescribing is a preventable risk factor. Explicit criteria such as the Beers criteria provide a valid instrument for describing the rate of inappropriate medication (IM) prescriptions among older adults.

Objective: To reduce IM prescriptions based on explicit Beers criteria using a nurse-led intervention in a nursing-home (NH) setting.

Study Design: The pre/post-design included IM assessment at study start (pre-intervention), a 4-month intervention period, IM assessment after the intervention period (post-intervention) and a further IM assessment at 1-year follow-up.

Setting: 204-bed inpatient NH in Bern, Switzerland.

Participants: NH residents aged ≥60 years.

Intervention: The intervention included four key intervention elements: (i) adaptation of Beers criteria to the Swiss setting; (ii) IM identification; (iii) IM discontinuation; and (iv) staff training.

Main Outcome Measure: IM prescription at study start, after the 4-month intervention period and at 1-year follow-up.

Results: The mean ± SD resident age was 80.3 ± 8.8 years. Residents were prescribed a mean ± SD 7.8 ± 4.0 medications. The prescription rate of IMs decreased from 14.5% pre-intervention to 2.8% post-intervention (relative risk [RR] = 0.2; 95% CI 0.06, 0.5). The risk of IM prescription increased nonstatistically significantly in the 1-year follow-up period compared with post-intervention (RR = 1.6; 95% CI 0.5, 6.1).

Conclusions: This intervention to reduce IM prescriptions based on explicit Beers criteria was feasible, easy to implement in an NH setting, and resulted in a substantial decrease in IMs. These results underscore the importance of involving nursing staff in the medication prescription process in a long-term care setting.

Background

Some medication-related problems in the growing population of older adults are considered preventable, especially those related to medications with an unfavourable benefit-to-risk ratio (labelled inappropriate medications [IMs]).[1-3] Identifying and discontinuing IMs is important particularly where there is evidence in favour of safer and equally effective alternative medications.[4,5] In 1991, Beers et al.[6] developed the first list of explicit criteria for IM use, and these were subsequently expanded and most recently updated in 2003.[7,8]

Explicit criteria, such as those in the Beers list,[6-8] have been used to describe the prevalence of IMs among older adults across various settings (community-dwelling, inpatient or nursing homes [NHs]), with reports ranging between 16% and 66%.[9-15] A variety of intervention studies, including randomized controlled trials, have focused on improving prescription patterns[16,17] and some have used explicit Beers criteria as outcome measures.[18-20] We found only two studies using explicit Beers criteria as a component of an intervention geared towards reduction of IMs.[21,22] One intervention conducted in a community-dwelling setting focusing on physicians reducing IM prescription among their patients showed a statistically significant but clinically small effect.[21] The other study found that use of a computer-based decision support system decreased the IM prescriptions in emergency departments.[22] Since the Beers criteria[6] were initially developed in an NH they may demonstrate their highest potential in institutional settings (hospitals, NHs). However, a recent systematic review found a lack of controlled studies for reducing IM use in NH settings.[23] Therefore, we conducted an intervention study to reduce IM prescription using the Beers criteria in an NH setting. Acknowledging the important role of nurses in the care of older adults in NHs we designed a nurse-led intervention.

Methods

Setting

This intervention was targeted at residents of a rural 204-bed inpatient NH in the canton of Bern, Switzerland. The intervention period lasted 4 months (1 May–31 August 2006) and had a 1-year follow-up (31 August 2007). All NH residents aged ≥60 years registered on at least one of the three data collection dates (pre-intervention 1 May 2006, post-intervention 31 August 2006, 1-year post-intervention 31 August 2007) were included in the study. During the study period 12 general practitioners, one psychiatrist and 72 registered nurses were responsible for resident medical care. The study protocol was approved by the local research ethics committee.

Data Collection

Data were collected pre-intervention (medications, sociodemographic and health-related characteristics), post-intervention (medications) and 1-year post-intervention (medications, sociodemographic and health-related characteristics). Resident medical records comprising NH practice (medications, sociodemographic and health-related characteristics) and physician records (diagnoses) were used for all data collection. Medications were recorded if they had been taken 7 days prior to data collection, used regularly, or on an as-needed basis. Trained research staff collected all data.

Table I. Key intervention elements with descriptions of a nurse-led intervention study to reduce inappropriate medication[a] (IM) prescriptions among older (aged ≥60 years) nursing-home (NH) residents in a Swiss NH

Adaptation of Beers list of IM prescriptions[8]
Removal of medications not available in Switzerland
Removal of clinically mandated medications if no alternative available in Switzerland
Compilation of list of medications with brand names available in Switzerland (IM list)
IM identification system for NH setting
Development of manual for identification of IMs by comparing residents' medication list with IM list
Written IM notification sent to nursing staff
IM discontinuation system for NH setting
Nursing staff provide initial verbal recommendation for discontinuation to prescribing physician at ward round
Prescribing physician decides on discontinuation based on clinical judgement
If IM not discontinued within 2 months, nursing staff initiates one-time verbal reminder to prescribing physician at ward round
Staff training
One-time (1 hour) geriatrician training of nursing head, nurse team leaders and prescribing physicians on study protocol, principles of IM, IM identification and IM discontinuation system
One-time (1 hour) nurse team leader training of nursing staff on implementation of IM discontinuation system

a Based on updated Beers criteria independent of diagnosis and conditions.[8]

Intervention

The key intervention elements with descriptions are listed in table I.

Adaptation of Beers Criteria

An IM list based on updated Beers criteria[8] independent of diagnosis or conditions was adapted for Switzerland. In brief, half of the medications described in the Beers criteria were found to be unavailable in Switzerland and were therefore excluded ([dextro]propoxyphene, indometacin, pentazocine, trimethobenzamide, methocarbamol, carisoprodol, chlorzoxazone, cyclobenzaprine, perphenazine/amitriptyline, quazepam, halazepam, dipotassium clorazepate, disopyramide, short-acting dipyridamole, methyldopa/hydrochlorothiazide, dicycloverine [dicyclomine], hyoscyamine, propantheline bromide, chlorphenamine [chlorpheniramine], cyproheptadine, promethazine, tripelennamine, pethidine [meperidine], ticlopidine, oxaprozin, Neoloid® [castor oil], orphenadrine, guanethidine, guanadrel, isoxsuprine, methyltestosterone, thioridazine, mesoridazine, etacrynic acid, desiccated thyroid). IMs were also excluded if there was no alternative available for clinically mandated treatment (i.e. diazepam 5 mg rectal suppository prescribed on demand for urgent treatment of epileptic seizure). The final IM list included 43 medications with brand names.

Inappropriate Medication Identification System

IMs were identified at all three data collection dates and for each resident admitted during the intervention period by comparison of residents' medication lists with the IM list. For every IM identified during the intervention period the research leader completed a written IM notification including the name of the resident, IM and prescribing physician, which was delivered to the responsible nursing team.

Inappropriate Medication Discontinuation System

Based on the IM notification the nursing team provided on subsequent medical rounds an initial verbal recommendation to the prescribing physician for discontinuing (stop, replace by, or change dosage) the IM. If the prescribing physician discontinued the IM, nurses updated the written IM notification (date, stopped or replaced by, or changed dosage) and returned it to the research staff for data entry. If the IM was not discontinued within 2 months the nursing staff initiated a one-time verbal reminder to the prescribing physician.

Staff Training

Before the intervention period a geriatrician trained (one time, for 1 hour) prescribing physicians (general practitioners and psychiatrists) and nursing team leaders on the study protocol, principles of IM, and IM identification and discontinuation systems. Nursing team leaders were then responsible for training (one time, for 1 hour) their nursing team.

Statistical Analyses

The main outcome measures were IM prescriptions after the intervention period of 4 months and at 1-year follow-up. Summary statistics (univariate, proportion and frequency) were used to describe the sociodemographic and health-related characteristics of the study population. Statistical analyses for differences between pre-intervention, post-intervention and 1-year post-intervention populations were performed using chi-squared (χ^2) tests for categorical variables and Student's t-test for continuous variables. Sensitivity analyses, recalculating IM prescription rates only in residents who lived in the NH at pre- and post-intervention and at pre-intervention and 1-year follow-up, were conducted. These analyses addressed the possibility that patients admitted during the study period could have been healthier and had fewer IMs, thereby attenuating IM prescription rates independently of the intervention.

All p-values were two-sided and values <0.05 were considered to be statistically significant. Poisson regression analyses were performed estimating relative risk (RR) and 95% confidence intervals. Data were analysed using STATA™ V10.0 (Stata Corp., College Station, TX, USA).

Results

Of 195 residents living in the NH on 1 May 2006, 173 met study inclusion criteria and were included in the pre-intervention population (figure 1). Twenty-two residents were admitted during the intervention period; 17 died or were discharged, leaving 178 residents in the post-intervention population. Subsequently, 181 residents registered on 31 August 2007 constituted the 1-year post-intervention population, 46 of whom were newly admitted over the 1-year follow-up period.

Pre-intervention and 1-year post-intervention populations did not differ statistically significantly on any sociodemographic or health-related characteristics (table II). Pre-intervention residents had a mean ± SD age of 80.3 ± 8.8 years, 51.4% were female and approximately half were dependent in all basic activities of daily living. On average, pre-intervention residents were prescribed a mean ± SD of 7.8 ± 4.0 medications.

The IM prescription rate decreased from 14.5% (95% CI 9.2, 19.7) [25/173] pre-intervention to 2.8% (95% CI 0.4, 5.3) [5/178] post-intervention (figure 2). Residents had a nearly 5-fold decreased risk of IM prescription post-intervention compared with pre-intervention (RR = 0.2; 95% CI 0.06, 0.5). The risk of IM prescription increased nonstatistically significantly in the 1-year follow-up period to 4.4% (95% CI 1.4, 7.4) [8/181; post-intervention vs 1-year follow-up, RR = 1.6; 95% CI 0.5, 6.1]. However, the risk of IM prescription when the pre-intervention and the 1-year post-intervention populations were compared showed a statistically significant decrease (RR = 0.3; 95% CI 0.1, 0.7).

Sensitivity analyses did not reveal relevant changes in results. In residents living in the NH both pre- and post-intervention the IM prescription rate declined from 15.4% (24/156) pre-intervention to 2.6% (4/156) post-intervention. When only those residents still living in the NH at 1-year follow-up were analysed, the IM prescription rate decreased from 17.4% (21/121) pre-intervention to 3.3% (4/121) at 1-year follow-up.

IMs identified at the three data collection dates are shown in table III. About two-thirds of all identified IMs were either benzodiazepines or antihistamines. Post-intervention, approximately one-third of all IMs were stopped without replacement and about one-half were replaced by appropriate medications according to the updated Beers criteria.[8] At post-intervention and 1-year post-intervention, benzodiazepines and antihistamines were still the most frequently prescribed IMs.

Discussion

In this pre/post-design study, IM prescriptions decreased substantially during a relatively short (4-month) intervention period. To our knowledge this is the first intervention study based on explicit Beers criteria demonstrating a relevant effect on reduction in IM prescriptions in an NH. The prescription rate of IMs showed a slight nonstatistically significant increase in the follow-up period after stopping the intervention.

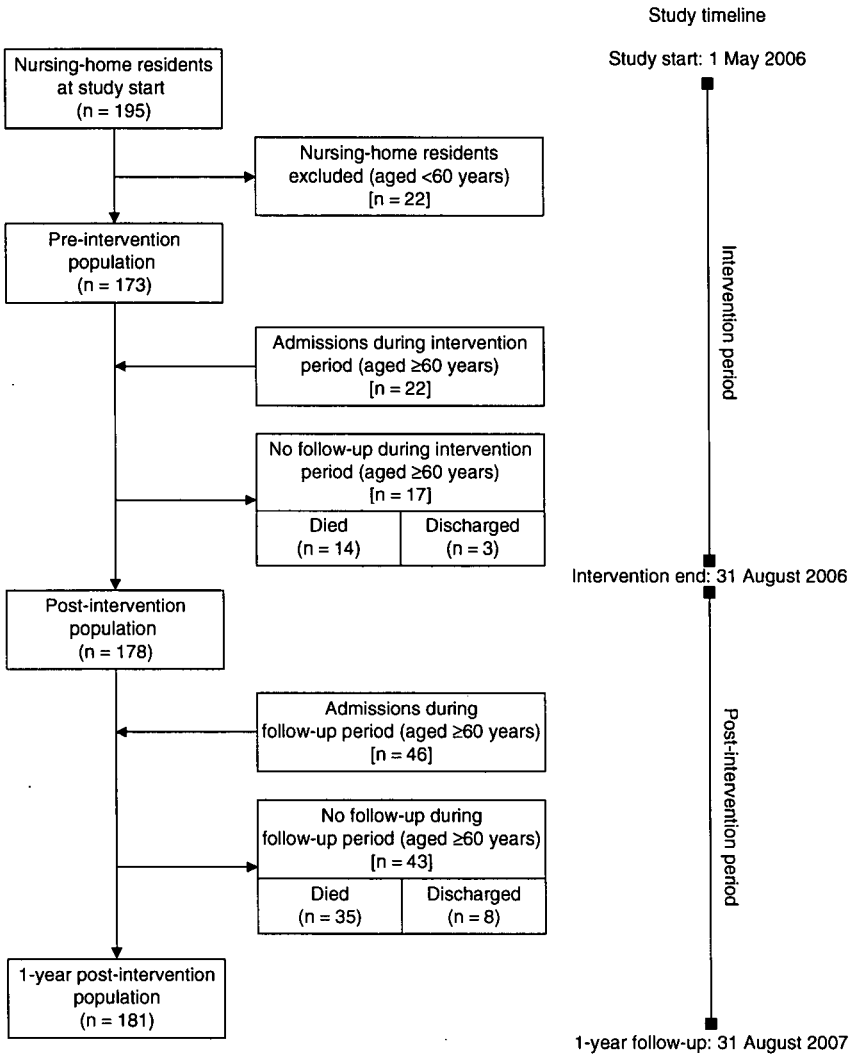

Fig. 1. Study population flowchart.

Our intervention was easy to implement in the NH setting and consisted of four key elements: (i) adaptation of Beers criteria; (ii) IM identification system; (iii) IM discontinuation system; and (iv) staff training. As in other studies conducted in Europe,[12,13] we initially had to adapt the Beers criteria to local circumstances because several medications in the Beers list were not available in Switzerland. Once an explicit list has been adapted an IM identification system can be customized to accommodate a wide variety of settings and in-place systems (e.g. paper-based, nurse-led, or automated electronic medical record-based systems). Focusing on identification of IMs is crucial. Recent publications have shown that choosing an appropriate instrument to identify IMs can influence the frequency of IM prescriptions.[19,25] However, the prescribing process extends beyond that; once an IM has been identified it is essential to have a system in place that ensures discontinuation or reduction to appropriate dosage levels. When developing a discontinuation

Table II. Characteristics of pre-intervention and 1-year post-intervention populations of a nurse-led intervention study to reduce inappropriate medication prescriptions among older (aged ≥60 years) nursing-home (NH) residents in a Swiss NH

Characteristic	Pre-intervention population (n = 173)	1-year post-intervention population (n = 181)	p-Value[a]
Demographic			
Age [y (mean ± SD)]	80.3 ± 8.8	80.4 ± 8.4	0.9
60–74 y [no. (%)]	48 (27.7)	46 (25.4)	
75–84 y [no. (%)]	66 (38.2)	79 (43.6)	
85–94 y [no. (%)]	56 (32.4)	49 (27.1)	
95–104 y [no. (%)]	3 (1.7)	7 (3.9)	
Female [no. (%)]	89 (51.4)	98 (54.1)	0.6
Married [no. (%)]	37 (21.4)	46 (25.4)	0.4
Health-related			
Charlson Comorbidity Index[24] score (mean ± SD)	2.1 ± 2.2	2.3 ± 2.3	0.5
0 [no. (%)]	45 (26.0)	44 (24.3)	
1–2 [no. (%)]	65 (37.6)	67 (37.0)	
3–4 [no. (%)]	40 (23.1)	42 (23.2)	
>4 [no. (%)]	23 (13.3)	28 (15.5)	
No. of medications (mean ± SD)	7.8 ± 4.0	8.3 ± 4.3	0.2
Care level			
low [no. (%)]	38 (22.0)	34 (18.8)	0.5
moderate [no. (%)]	57 (32.9)	47 (26.0)	0.2
high [no. (%)]	78 (45.1)	100 (55.2)	0.06

a Differences between characteristics of populations were tested with the chi-squared (χ^2) test for categorical variables and Student's t-test for continuous variables.

system it is fundamental to account for setting-specific prescription processes.[16] Our results show promising effects when NH nursing staff are included in this process.

Several limitations of this study should be considered. First, this study was conducted in a single small rural NH population, limiting the generalizability of our findings to other NHs or more broadly to other settings. Second, results of pre/post-design, nonrandomized, controlled studies must be interpreted with caution because unidentified unbalanced factors influencing the results cannot be excluded. However, since there were no other systemic changes in the NH, the reduction in IM prescriptions observed in our study is most likely to be primarily the result of our intervention. Third, other studies have shown some limitations of the Beers criteria: explicit Beers criteria identify only the 'tip of the iceberg' of IM prescriptions that lead to adverse drug reactions,[26] it is unclear whether a reduction in IM prescriptions actually improves clinical outcomes,[16,27-29] and some studies have shown that Beers criteria medications do not necessarily increase the risk of adverse drug reactions.[29,30] Therefore, it is possible that reducing the use of these medications had a limited impact on improving clinical outcomes in patients. Furthermore, the duration and intensity of the intervention was limited, and a longer or more intense

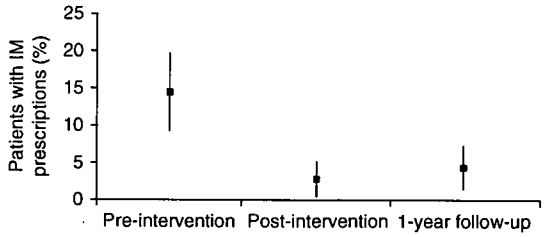

Fig. 2. Proportion of patients with inappropriate medication (IM) prescriptions and 95% confidence intervals at pre-intervention, post-intervention and 1-year follow-up.

Table III. Description and number of inappropriate medication[a] (IM) prescriptions at pre-intervention, post-intervention and 1-year follow-up data collection timepoints in a nurse-led intervention study to reduce IM prescriptions among older (aged ≥60 years) nursing-home (NH) residents in a Swiss NH

Category	Agent	No. of IMs				
		pre-intervention	stopped, no replacement	replaced by (agent)	post-intervention	1-year post-intervention
Long-acting benzodiazepines	Diazepam	4	3	1 (zolpidem)		1
	Flurazepam	3		1 (zolpidem)	2	
Short-acting benzodiazepines	Lorazepam	3	2		1	2
Antipsychotics	Thioridazine	2	2			
Tricyclic antidepressants	Amitriptyline	3	1	2 (trazodone)		
	Doxepin	1		1 (mianserin)		
Antiarrhythmics	Amiodarone	1			1	1
	Digoxin	1	1			
Antihypertensives	Short-acting nifedipine	1		1 (long-acting nifedipine)		
Antihistamines	Hydroxyzine	10	2	7 (fexofenadine)	1	3
	Diphenhydramine	1		1 (zolpidem)		
NSAIDs	Indometacin					1
Laxatives	Bisacodyl					1
Total		**30**	**11**	**14**	**5**	**9**

a Based on updated Beers criteria independent of diagnosis and conditions.[8]

intervention may have had more prolonged effects on the prescription rate of IMs. Finally, given the fact that the NH residents included in this study were cared for by 13 different physicians, the intervention effect may have been even larger if one physician had administered NH care.

Since we conducted our study other screening tools for identifying older persons receiving IMs have been developed and tested.[31,32] For example, the STOPP (Screening Tool of Older Persons' potentially inappropriate Prescriptions) instrument has been shown to identify a significantly higher proportion of European patients requiring hospital care because of IM-related adverse events than the Beers criteria.[32] Based on these findings it is conceivable, but unquantifiable, that use of the Beers criteria in this European study may have underestimated IM prevalence. However, an important strength of our intervention is that it can be easily adapted to incorporate the latest evidence by using newer tools (e.g. STOPP) instead of the Beers criteria.

There is a need for well designed prospective studies to evaluate other intervention designs (i.e. longer duration, more intense, other settings, newly developed European criteria as opposed to the Beers criteria) as well as the impact of reducing IMs not only based on the number of IM prescriptions but also in relation to health- and quality of life-related outcomes.

Conclusions

Despite the limitations of our study, our findings suggest that an intervention to reduce IM prescriptions based on explicit Beers criteria is feasible and inexpensive to implement in an NH setting. The study also adds evidence to current data on interventions to reduce IM use,[22] namely that reduction of IM use is not solely the action of a physician, but rather involves interdisciplinary work and development of a support system. The results underscore the importance of involving both physicians and nursing staff in the medication prescription process in a long-term care setting.

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Medication Safety

Using Lean to Improve Medication Administration Safety: In Search of the "Perfect Dose"

Joan M. Ching, RN, MN; Christina Long, RN, BSN; Barbara L. Williams, PhD; C. Craig Blackmore, MD, MPH

Medication errors remain one of the most common errors in hospitals and contribute to the more than 770,000 adverse drug event–related injuries and deaths each year in the United States.[1–3] Hospitals spend an estimated $4 billion annually to treat iatrogenic adverse drug events.[3] According to one study, one in seven hospitalized Medicare beneficiaries experienced a serious adverse event, 31% of which were attributed to medication, and half of all fatalities occurred either as the result of improper medication administration (wrong drug or wrong dosage) or inadequate treatment of known side effects.[4] Not all adverse drug events can be avoided. However, the Adverse Drug Events Prevention Study Group found that preventable medication errors are most often made at the prescribing and administration phases (56% and 34%, respectively).[5] Although pharmacists and nurses intercept nearly one half of all prescribing errors, very few errors committed during the medication administration process are intercepted because there is no one except the patient to intercept the errors.[5]

Although medication administration errors pose a major problem, quantifying them has proved elusive because most errors go undetected and are vastly underreported in hospital incident reporting systems.[6] Direct observation of medication administration is a practical medication-error detection method and produces valid, reliable results.[7] The Collaborative Alliance for Nursing Outcomes (CALNOC) Medication Administration Accuracy Quality Study promotes quantification of practice violations and medication errors through direct observation as nurses administer medicines to their patients.[8] Several studies have used direct observation to target system factors and work conditions often cited by nurses as primary causes of medication administration errors.[9]

We focused on similar system factors and applied the Virginia Mason Production System (VMPS), a health care application of the Toyota Lean manufacturing approach[10–12] to streamline the medication administration process and eliminate the errors identified through the CALNOC approach. VMPS is a management

Article-at-a-Glance

Background: At Virginia Mason Medical Center (Seattle), the Collaborative Alliance for Nursing Outcomes (CALNOC) Medication Administration Accuracy Quality Study was used in combination with Lean quality improvement efforts to address medication administration safety.

Methods: Lean interventions were targeted at improving the medication room layout, applying visual controls, and implementing nursing standard work. The interventions were designed to prevent medication administration errors through improving six safe practices: (1) comparing medication with medication administration record, (2) labeling medication, (3) checking two forms of patient identification, (4) explaining medication to patient, (5) charting medication immediately, and (6) protecting the process from distractions/interruptions.

Results: Trained nurse auditors observed 9,244 doses for 2,139 patients. Following the intervention, the number of safe-practice violations decreased from 83 violations/100 doses at baseline (January 2010–March 2010) to 42 violations/100 doses at final follow-up (July 2011–September 2011), resulting in an absolute risk reduction of 42 violations/100 doses (95% confidence interval [CI]: 35–48), $p < .001$). The number of medication administration errors decreased from 10.3 errors/100 doses at baseline to 2.8 errors/100 doses at final follow-up (absolute risk reduction: 7 violations/100 doses [95% CI: 5–10, $p < .001$]). The "perfect dose" score, reflecting compliance with all six safe practices and absence of any of the eight medication administration errors, improved from 37 in compliance/100 doses at baseline to 68 in compliance/100 doses at the final follow-up.

Conclusion: Lean process improvements coupled with direct observation can contribute to substantial decreases in errors in nursing medication administration.

Sidebar 1. The Collaborative Alliance for Nursing Outcomes (CALNOC) Medication Administration Accuracy Quality Study

CALNOC is a collaborative alliance targeted at nursing care processes and patient outcomes. The CALNOC Medication Administration Accuracy Quality Study focuses on the administration of medications by nurses to hospitalized patients. The primary outcome of the study is medication administration accuracy—that is, the administration of a medication as it was ordered. An error is a dose administered differently than ordered in the patient's chart.

Data collection in CALNOC is through naïve observation:

The nurse auditor does not know the actual medications being prepared and administered but works with the observed nurse to determine the names/dosages of the medications after they are given. Compliance with six safe practices is observed and recorded.

Verification of administration accuracy is through comparative record review:

The nurse auditor compares what was observed with what was ordered in the medical record to determine if there were any administration errors.

Source: Collaborative Alliance for Nursing Outcomes (CALNOC). *Medication Administration Accuracy Quality Study Definitions, Codebook 2012, Part I.* San Ramon, CA: CALNOC, 2012.

method to systematically identify and eliminate waste and inefficiency in all processes that are a part of health care delivery.

For this investigation, we employed the CALNOC approach (Sidebar 1, above) to measure the number of safe-practice violations and medication errors across 13 inpatient units before and after completing a series of improvements using VMPS Lean tools.

Methods

This investigation was performed as part of a quality improvement (QI) project, and a waiver was granted from our Institutional Review Board. All data with patient-specific information were securely handled and de-identified before analysis.

Setting

The study was conducted at the Virginia Mason Medical Center (VMMC), a 336-bed hospital (Seattle) with 17,000 annual inpatient admissions. Participating units included 10 acute care units, ranging from 20 to 29 beds; one 33-bed ICU; one 18-bed adult rehabilitation unit; and one 17-bed emergency department. There are no pediatric or obstetrics units in our setting. Computerized provider order entry and electronic medication administration record, along with automated dispensing cabinets (ADCs) housed in each unit's medication supply room, have been in place on every unit since 2005.

Planning the Interventions

Lean improvement begins with direct observation of the work area to understand the current process. We accomplished this in a uniform way by initiating the CALNOC Medication Administration Accuracy Quality Study in January 2010.[8] In addition, we performed small-scale, time-motion studies to determine the component steps in the medication administration process, the time required for medication administration, and the walking steps for individual nurses to withdraw medications from the ADC and administer them to patients. We also solicited patient feedback about their unmet expectations when receiving medicines. From this information, we constructed a Lean value stream map[13] of the medication administration process and identified improvement opportunities to remove waste and inefficiency within the process (Appendix 1, available in online article).

Key to eliminating waste under the Lean approach is the understanding that staff members who do the work know the problems and have the best ability to find solutions. Thus, from April 2010 through March 2011, more than 100 frontline staff members from nursing, medicine, pharmacy, nutrition services, engineering, and informatics, as well as former patients participated in a series of Lean rapid process improvement teams focusing on specific problem areas uncovered by the CALNOC study (Figure 1, page 197). Two-day *Kaizen* Events and five-day Rapid Process Improvement Workshops (RPIWs) were facilitated by VMPS–trained leaders to help the team apply VMPS methods, test ideas, and spread the agreed-on solutions across units. These events are detailed in Table 1 (pages 198–199), with more comprehensive discussion of the Medication Preparation Standards RPIW in Sidebar 2 (page 200). The entire effort was supported as an institutional priority by the VMMC CEO and executive leaders.

Lean Improvements

The medication administration team applied Lean improvement concepts (Table 2, page 202) in three broad categories: improving the medication room layout, applying visual controls, and standardizing nursing work.

Improving the Medication Room Layout. In March 2010 we applied the VMPS Flows of Medicine to improve the work flow within the medication room where ADCs for medications were secured. In brief, use of the VMPS Flows of Medicine involved a team's tracking and recording on a graphic representation of the work area the process (or flow) for each of the important components of medical care: patients, providers, family and relationships, medications, supplies, equipment, information, and

Lean Process Improvement Events During the Study Time Frame, December 2009–Quarter 3, 2011

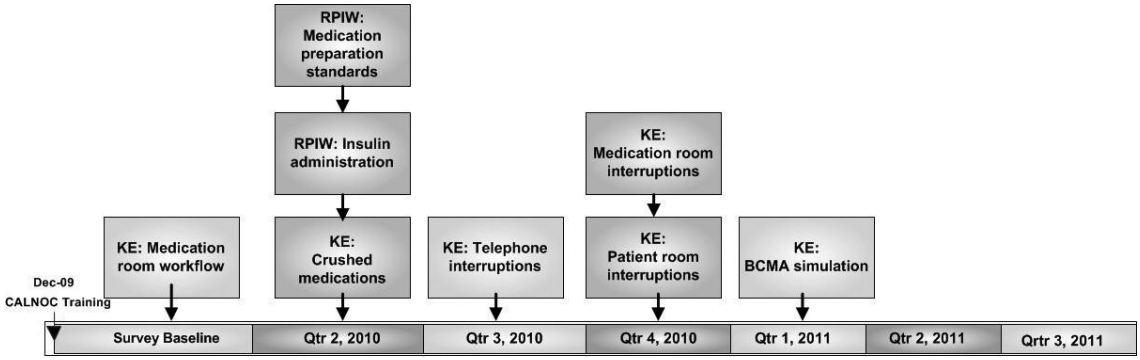

Figure 1. *From March 2010 (survey baseline) through March 2011 (Quarter 1), more than 100 frontline staff members from nursing, medicine, pharmacy, nutrition services, engineering, and informatics, as well as former patients participated in a series of Lean rapid process improvement teams. CALNOC, Collaborative Alliance for Nursing Outcomes; RPIW, rapid process improvement workshop; KE,* Kaizen *(improvement) Event; BCMA, bar code medication administration.*

process engineering.[14] For this project, the team used a different-colored pencil to trace on paper the flow of nurses, medications, supplies, and information. "Nursing flow lines" revealed wasted motion as nurses walked back and forth between the ADC and shelves, searching for medication supplies in a cluttered and disorganized medication room. By providing a physical recording of each flow, the Flows of Medicine exercise provided clues on how to eliminate defects and associated rework by illuminating inconsistencies in the process.

The team tested several designs and selected a U-shape, unidirectional work area or "cell" that required a nurse to take fewer steps when withdrawing medications from the ADC, retrieving supplies or labels, and securely conveying medications out of the room (Appendix 2, available in online article). This layout exemplified Just in Time delivery (right item, right time, right quantity, right place) with minimal waste or rework, and more efficient Flows of Medicine.

From April through August 2010, teams of supply chain staff, engineers, pharmacists, and information technology specialists helped us to rearrange the contents of 17 medication rooms throughout the entire hospital. On average, minimally redesigning a room took between two and three days of work, with purposeful avoidance of remodeling activity during peak medication administration periods. Staff welcomed the improvements and offered suggestions on how to further tailor the room layout to meet their unique needs.

Applying Visual Controls. Borrowing the "sterile cockpit" model during aircraft takeoff and landing, the improvement team sought to promote a "quiet zone" within the busy medication room so nurses could concentrate when withdrawing medications from the ADC.[15] After testing several different methods of visual control, we decided to hang a large "No Talking Zone" sign in the middle of the room as a reminder to refrain from talking when the nurse is at the ADC (Appendix 3, available in online article). We also used red floor tape to physically designate "a zone of silence" around the ADC where team members could not distract or interrupt a nurse.

In addition, we applied the Lean concept of *andon* (a signal to identify line stoppage)[16] in several medication rooms by installing outside of the medication room an indicator andon light that was triggered by a motion detector in front of the ADC (Appendix 2). A nurse walking up to and standing in front of the ADC causes the outside indicator light to turn on. Thirty seconds after the nurse walks away, the andon light turns off. Staff members were able to see whether the andon is on or off and thereby adjust their actions, resulting in reduced traffic and distraction levels within the medication room.

Standardizing Nursing Work. We employed the Lean concept of standard work, a sequence of steps within a process that is repeatable by all who perform the work.[10,16] Nurses make fewer errors and experience less rework when they follow these six steps of medication administration[8]:

1. Compare medication with medication administration record on removal from ADC.
2. Keep medication labeled from preparation to administration.
3. Check two forms of patient identification.
4. Explain medication to patient.
5. Chart medication immediately after administration.
6. Protect the process from distractions/interruptions.

Table 1. Lean Process Improvement Events*

KE: Medication Room Work Flow

Targeted Cycles: 1, 2†

Rationale

A cluttered, disorganized medication room made it difficult for nurses to retrieve medications. Nurses waiting in line for the ADC created a distraction for the nurse actively retrieving medications. Consequently, retrieving the wrong dose or forgetting supplies necessitated a return to the medication room and redoing work.

Actions Taken

The team mapped the flows of nurses, medications, information, and supplies within the medication room. A U-shape cell (Appendix 2) was created so the ADC and supplies were arranged in the sequence of nursing work flow. Shelves were built above a preparation station to house point-of-use supplies.

Success/Challenges

68% reduction in time from when the nurse entered and exited the medication room. 100% reduction in (1) the number of nurses waiting to use the ADC and (2) interruptions or distractions observed at the ADC.

RPIW: Insulin Administration

Targeted Cycles: 2, 5, 6

Rationale

Attempts to meet patient needs for on-demand meals were frustrated by lack of coordination between clinical staff and the food service department. Patients who needed help with blood glucose management were not getting blood tests or insulin before meals.

Actions Taken

With the patient's active involvement, the team created and tested a sequenced process that coordinated the patient's meal order, blood glucose testing, pre-meal insulin administration, and delivery of the meal to the bedside. This system was triggered by the actual order from the patient.

Success/Challenges

Better communication resulted between the patients, nursing staff, and food service personnel, and the patient remained in control of the meal schedule. The new process was spread hospitalwide within 60 days, but full implementation was dependent on creating an electronic interface between our on-demand meal service and EMR.

KE: Crushed Medications

Targeted Cycles: 2, 4–7

Rationale

Nurses spent unnecessary time crushing solid medications for patients with enteral tubes when liquid forms were already available. Additional time was spent troubleshooting clogged enteral tubes. Some nurses did not know where to find the "Do Not Crush" list or how to safely administer multiple medications.

Actions Taken

The team developed standard processes for pharmacists to help physicians order liquid medications and for nurses to deliver enteral medications based on best practice (American Society for Parenteral and Enteral Nutrition). Kits containing a patient-specific pill crusher, sterile water, syringes, and cups were created and kept at the patient's bedside.

Success/Challenges

The team saw an initial reduction in medication administration delays. However, failure of pill crushers in trials by team members limited success. Without a pill crusher at the patient's bedside, one-piece flow was thwarted. The team reconvened to do further troubleshooting.

KE: Telephone Interruptions

Targeted Cycles: 1–7

Rationale

Telephone calls from patient's family members, friends, physicians, and other departments were indiscriminately directed to nurses when they were administering medications. These interruptions increased the risk of errors.

Actions Taken

The team created a triage tool to help the unit secretary differentiate urgent from nonurgent phone calls. The team also developed a message template for recording nonurgent information and a respectful response for the caller. Finally, the team designed a visual control board to enable nurses to signal the start and finish of medication delivery. Nurses then picked up messages for telephone follow-up.

Success/Challenges

34% reduction in telephone interruptions during periods of peak medication administration. Units sustained the use of the visual control board in a 90-day period and recording nonurgent messages for nurses; however, success was dependent on individuals consistently following standard work.

KE: Medication Room Interruptions

Targeted Cycles: 1, 2

Rationale

Staff were unaware that talking to or interrupting a nurse who is working at the ADC could contribute to a medication error. Likewise, nurses did not appreciate that multitasking during medication retrieval substantially increased the risk of committing a medication error.

Actions Taken

The team designed a "See-Feel-Change" campaign so staff avoid interruptions. It created and tested a "No Talking Zone" sign in the medication room and "While You Were Giving Meds" notepad for recording nonurgent messages during peak medication administration periods. The team negotiated a time for ADC restocking and supply delivery during off-peak hours.

Success/Challenges

65% reduction in interruptions at ADC at 90 days. Staff agreed to "no interruption" behavior in medication room (for example, waiting outside the medication room if the ADC was in use). "No Interruption" signage and red floor demarcations were spread to all 13 units.

(continued on page 199)

Table 1. Lean Process Improvement Events (continued)*

KE: Patient Room Interruptions

Targeted Cycles: 3–7

Rationale

Physicians and staff interrupted nurses as they administered medications at the bedside. Similarly, nurses had difficulty concentrating on accurate medication administration when patients and families interrupted with their questions and concerns.

Actions Taken

The team sorted patient-room interruptions into three categories (emergent; able to wait 5–10 minutes; able to wait > 10 minutes) and created a response for each. The team built on a previous KE's message template to communicate nonurgent messages. It also developed a visual control to serve as a physical barrier at patient room entry and respectful feedback approach to staff that chose not to observe the visual control.

Success/Challenges

76% reduction in interruptions at the bedside. When patients and family members understood the nurse's needs for full concentration, they readily partnered. Often, nurses forgot to put the visual control at the door before giving medications, so intrusions were common.

KE: Bar Code Medication Administration (BCMA) Simulation

Targeted Cycles: 1–4

Rationale

Implementing barcode scanning of medications was anticipated to change the nursing work flow and introduce new equipment. Other concerns were to avoid alienating the patient with additional electronics and to involve the patient in medication delivery.

Actions Taken

The team performed multiple simulations of bar code scanning using the concept of one-piece flow. It then developed a standard process for more complex medication delivery for patients with transmission-based precautions. The team developed countermeasures for anticipated common clinical scenarios.

Success/Challenges

Standard processes created in this KE were incorporated into BCMA curriculum for nurse training. Simulations allowed us to discover work flow issues that needed to be addressed before implementing BCMA.

* An additional RPIW on Medication Preparation Standards is discussed in detail in Sidebar 2. KE, *Kaizen* Event; RPIW, Rapid Process Improvement Workshop; ADC, automated dispensing cabinet; EMR, electronic medical record.

† The targeted cycles refer to specific nursing cycles of work, as shown on the Value Stream Map of the Medication Administration Process (Appendix 1, available in online article).

Using a contrastive learning method to educate nurses to this standard work, our nurse auditors developed "Do" versus "Do-Not-Do" posters, which displayed unambiguous actions with relatively few words for each safe practice. In addition, every poster featured the tagline, "Every Patient. Every Medication. Every Time." to convey the expectation of adhering to standard work (Appendix 4, available in online article). Posters were distributed to and displayed on all nursing units.

To encourage nurses to adopt the safe practice standard work, we posted individual-unit quarterly dashboards so they could identify whether they were moving closer to or farther from identified targets relative to other hospitals using the same CALNOC study (Appendix 5, available in online article).

Evaluation Methods

Study Design. To evaluate the effectiveness of our Lean interventions, we performed a cohort study in which medication error rates were compared during a 21-month period encompassing the intervention. The study was based on prospectively collected data using the CALNOC Medication Administration Accuracy Quality Study methods.[8]

The effects of the intervention were evaluated through direct observation of nurse safe practices and assessment of medication administration errors. Trained audit nurses determined the accuracy of 100 medication doses per quarter on each of 13 nursing units by comparing their observations to provider orders found in the medical record. Nurse auditor training consisted of a two-hour course on the survey process, practicing with observation code sheets, and coaching about scoring nuances by CALNOC personnel. A total of 70 nurses were trained as auditors—approximately 6 per nursing unit—with use of the VMMC adaptation of the CALNOC Medication Administration Accuracy Quality Study Codesheet (Appendix 6, available in online article). We did not evaluate the effects of the intervention by unit because none of the units appeared to have outlying data.

The CALNOC Medication Administration Accuracy Quality Study has been reported previously.[8,9,17–19] In brief, nurses working on inpatient units were informed about the general nature of the quality study and were told that observations would be made by trained audit nurses who work on their respective units. For each observed dose, following assent of the nurse to be observed and introduction of the audit nurse to the patient, the audit nurse would observe each step of the medication administration process, recording violation of any of the six safe practices. Following medication administration, the nurse compared the medications ordered in the patient's medical record with

Sidebar 2. Medication Preparation Standards Rapid Process Improvement Workshop

The medication room U-shaped cell developed at the Medication Room Work Flow *Kaizen* Event not only improved nursing efficiency but exposed resistant practice. At the automated dispensing cabinet (ADC), for example, nurses were either constantly interrupted or themselves distracted by competing demands for their attention. Sometimes nurses chose not to label syringes or prematurely removed medications from their packaging. To avoid being tardy with medication delivery, some withdrew medications from the ADC for more than one patient at a time. To address these practice variations that posed a threat to patient safety, a team of seven nurses and one pharmacist participated in a five-day Rapid Process Improvement Workshop (RPIW) in April 2010, which focused on embedding safety standards when nurses retrieve and prepare medications. During the course of the RPIW, the team members gathered together to intensively study and improve on broken or defective processes.

The work plan for a Virginia Mason Medical Center RPIW is standardized. The focus area, executive sponsor, workshop leader, and team leader were identified eight weeks before the workshop. Five weeks before, the team leader observed the process at least 10 times, determining the baseline value stream, nursing actions, and associated cycle times. With the guidance of the executive sponsor, two weeks before the workshop, the RPIW leaders finalized targets to direct the team's focus and efforts (*see* Table, below). The first day of the RPIW consisted of Virginia Mason Production System (VMPS) education for the entire team, led by a VMPS Certified Leader. Days 2 to 4 were devoted to work on the future state value stream, process improvements, and tools, with daily debrief sessions and a midweek report-out to the process owner. On the Day 5, the entire team delivered the final report in person to the institution.

During the workshop week, the team was challenged to ask "why?" as they reviewed data about interruptions, distractions, and medications observed to be unlabelled, unattended, or withdrawn from the ADC for more than one patient at a time. The nurses on the team stated that they themselves had faced these challenges. One nurse showed the team how the medication preparation station lacked preprinted labels for the most frequently used injectable medications. This required her to handwrite a label each time. Another nurse demonstrated how difficult it was to politely decline a conversation when another staff member at the ADC asked questions. The team then generated and tested ideas during the next few days until the workshop's targeted metrics showed substantial improvement.

At the workshop's conclusion, the executive sponsor and RPIW leaders met with the nurse manager (process owner) of the two affected units to agree on the work breakdown structure, communication plan, and implementation time line. Changes were rolled out during a 90-day experience, with measurement and reporting of outcomes at 30-, 60-, and 90-day intervals. At the 60-day mark, both units had reduced interruptions and distractions at the ADC by 30%. There were no observations of nurses withdrawing more than one patient's medications at a time or leaving medications unattended. Medications exiting the medication room were consistently labeled and transported in compostable trays to the bedside. Finally, the medication preparation station was kept organized and well stocked with the assistance of our distribution department. Workshop improvements were spread throughout the hospital and later spawned multiple, two-day Kaizen Events related to reducing interruptions on other nursing units.

Baseline and 60-Day Metrics for Medication Preparation Standards

Metric	Baseline	60-Day Remeasure	Team Actions
Quality Defects			
1. % of Time RN is Interrupted/Distracted During Medication Preparation	100%	70%	Tested "no interruption" visual controls; proposed installing motion detector in front of automated dispensing cabinet (ADC)
2. % of Time RN Withdraws Medications for > 1 Patient at a Time	30%	0%	Included this safe medication principle in visual control at ADC
3. % of Time Medication Is Left Unattended	10%	0%	Included this safe medication principle in visual control at ADC; used compostable food tray to convey medications to patient bedside
4. % of Time Medication Is Not Labeled	20%	0%	Created standard work so that all oral, crushed, and injectable medications remain labeled until administered; sorted unit's most frequently used injectable medications and stocked preprinted labels at the medication preparation station

medications administered to determine if any medication administration errors had occurred. Medication administration errors were categorized as (1) unauthorized medication, (2) wrong dose, (3) wrong form, (4) wrong route, (5) wrong technique, (6) extra dose, (7) wrong time, and (8) medication not available (Table 3, page 202).

Interactions between the trained audit nurse and observed nurse were limited to those defined in the CALNOC study methods.[8] Should the audit nurse observe a potentially dangerous event if medication administration were to continue, he or she would immediately interrupt the process by inviting the nurse to step away from the patient bedside and quietly advise the nurse of the concern outside the patient's room. This was a rare occurrence. If an error was discovered in record review that

was likely to be repeated, the audit nurse would alert the observed nurse and explain the finding. In addition, the audit nurse was encouraged to discuss the error with the unit manager so action can be initiated at a systems level.

Outcome Measures. The study outcomes were adherence to the six safe practices and identification of the eight medication administration errors. A "perfect dose" score would reflect 100% compliance with the safe practices and absence of medication administration errors.

Data Analysis. We analyzed adherence to safe practices and rates of medication administration errors during the entire study period and specifically for the baseline period (January 2010–March 2010) compared with the final follow-up period (July 2011–September 2011). We summarized the rate of safe-practice violations per 100 doses per quarter and the rate of medication administration errors per 100 doses per quarter. Significant changes from baseline to follow-up values in continuous variables were determined using *t*-tests. Significant changes of dichotomous variables were determined using chi-square. Linear and logistic regression analyses were used to evaluate temporal trends in error rates during the 21-month period (January 2010–September 2011). Statistical analysis was performed using STATA 10 (Stata Corp, College Station, Texas).

Results

Patients

Trained nurses observed a total of 9,244 doses on 2,139 unique patients in the 21-month period. The mean age of the patients observed was 63 years (range, 18–110 years), and 53% of them were women. Because multiple doses may be observed on the same patient, nursing units with longer lengths of stay contributed fewer patients (but similar numbers of doses) to the total. The mean number of doses per patient was 4.3 (standard deviation = 3.9, range, 1–30).

Safe-Practice Violations

As shown in Figure 2 (above, right), following the intervention, the number of safe-practice violations decreased from 83 violations/100 doses at baseline (*N* = 1,282 doses) in January–March 2010 to 42 violations/100 doses at final follow-up (*N* = 1,238 doses) in July–September 2011 (absolute risk reduction: 42 violations/100 doses (absolute risk reduction: 42 violations/100 doses [95% confidence interval (CI): 35–48, $p < .001$]) (Figure 3, page 203). The most common safe-practice violation at baseline was distractions (580/1,066 [54%]). Not checking two forms of identification (154/1,066 [14%]) and not explaining the medication to the patient (136/1,066 [13%])

Safe-Practice Violations by Quarter per 100 Doses (*N* = 9,244 Doses), January–March (Quarter 1) 2010–July–September (Quarter 3) 2011

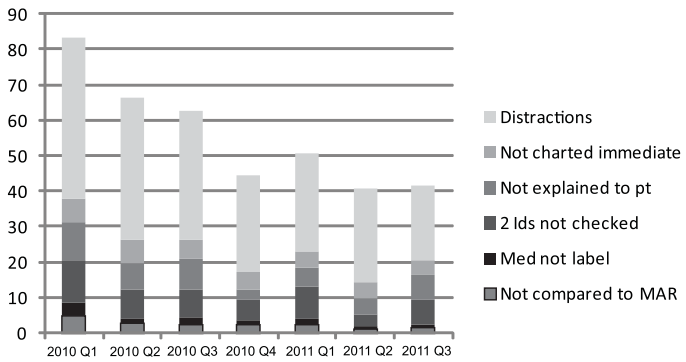

Figure 2. *Following the intervention, the number of safe-practice violations decreased from 83 violations/100 doses at baseline (*N *= 1,282 doses) in January–March 2010 to 42 violations/100 doses at final follow-up (*N *= 1,238 doses) in July–September 2011 (absolute risk reduction: 42 violations/100 doses [95% confidence interval: 35–48,* p < *.001]). Id, identification; pt, patient; MAR, medication administration record.*

were also common. The largest decreases between baseline and final follow-up occurred in the "comparing medication to the medication administration record" ($p < .001$) and "labeling medication" categories ($p < .001$).

During the 21 months (or seven-quarter period) represented in the linear regression analysis, there were significant decreases in each of the six safe-practice violation categories ($p < .001$) and in the sum of the safe-practice violations: (rate of risk reduction: 6.8 violations/100 doses per quarter [95% CI: 6.0–7.6, $p < .001$]).

Medication Administration Errors

Figure 3 (page 203) shows the breakdown of medication administration errors by quarter. Following the intervention, the total number of medication administration errors decreased from 10.3 errors/100 doses at baseline to 2.8 errors/100 doses at final follow-up (absolute risk reduction: 7.5 errors/100 doses [95% CI: 5–10, $p < .001$]). There were a total of 132 medication administration errors at baseline, the most common of which was "wrong time," which accounted for 86 (65%) of all 132 medication administration errors.

During the entire seven-quarter study, there was a decrease in the total quarterly medication administration errors (rate of risk reduction: 1.0 errors/100 doses [95% CI: 0.7–1.2, $p < .001$]), as well as in the error categories of "wrong dose" ($p =$

Table 2. Lean Concepts*

Lean Concept	Definition	Medication Administration Example
VMPS Flows of Medicine	Fundamental components of any process that flow together to create the patient's experience: (1) patients, (2) providers, (3) family and relationships, (4) medications, (5) supplies, (6) equipment, (7) information, and (8) process engineering	The flow of nurses, medications, supplies, and information within the medication room (Appendix 2)
Just inTime	Delivery of supplies, equipment, or information when it is needed in the right quantity needed	Stationing medications, supplies, and equipment in the right amount and in the sequence of the nurse's work flow
U-shape cell	Configuration of work processes so that work is sequenced in a U-shaped format to maximize efficiencies	Medication room layout with ADC and supplies at point of use to reduce wasted motion (Appendix 2)
Andon	Visual control system that reflects the status of the process or worker	"No Talking Zone" sign (Appendix 3), red floor demarcation, indicator light outside medication room
Standard work	Sequencing of steps within a process that is repeatable by all who perform the work	Six safe medication administration practices
Workplace inspection (go and see)	Intently observing the area where work is performed	CALNOC Medication Administration Accuracy Study

* VMPS, Virginia Mason Production System; ADC, automated dispensing cabinet; CALNOC, Collaborative Alliance for Nursing Outcomes.

Table 3. Eight Medication Error Types and Examples*

Medication Errors	Examples
Unauthorized drug: Administered dose that was never ordered	■ No written order for administered medicine ■ Order entered only after nonurgent pain medicine given
Wrong dose: Administered dose containing the wrong number of preformed dosage units	■ One pill given when two pills had been ordered ■ At patient's request, half the oral dose given without reconciling the dosage change with the prescriber
Wrong form: Administered dose in a different form than specifically ordered	■ Tablet given when a suspension had been ordered
Wrong route: Administered dose using a different route than ordered	■ Sublingual dose given orally ■ Nasal spray given in same nostril despite order to alternate nostrils
Wrong technique: Use of an inappropriate procedure or improper technique that can alter drug effect	■ Patient's blood pressure not measured before antihypertensive medicine given ■ Extended-release medicine crushed and given via feeding tube
Extra dose: Administered dose given in excess of the total number of times authorized	■ Medicine continues to be given despite discontinue order on record ■ Pain medicine dose given in excess of range order
Wrong time: Administered dose > 60 minutes before or after the scheduled time	■ Self-explanatory
Drug not available: Administered dose > 60 minutes after the scheduled time because of drug nonavailability	■ Self-explanatory

* An *error* is defined as a dose administered differently than ordered on the patient's medical record. An error may or may not result in harm to a patient.

.050), "wrong technique" (p = .001), and "wrong time" (p < .001).

The "perfect dose," reflecting compliance with all six safe practices and absence of any of the eight medication administration errors improved from 37 in compliance/100 doses (476/1,282) at baseline to 68 in compliance/100 doses (846/1,238) at the final quarter (absolute risk reduction: 31 in compliance/100 doses [95% CI: 27–35, p < .001]) (Figure 4, page 203).

Discussion

In this article, we detail substantial and statistically significant decreases in errors in both nursing processes and medication administration following a series of Lean quality improvements. Overall, the rate of perfect doses increased by 84%—from 37% to 68%— between baseline and final follow-up. Our quality improvements used Lean principles of flow to improve the physical layout of the medication room, visual controls (including

Medication Administration Error Types by Quarter per 100 Doses (*N* = 9,244 Doses), January–March (Quarter 1) 2010 Through July–September (Quarter 3) 2011

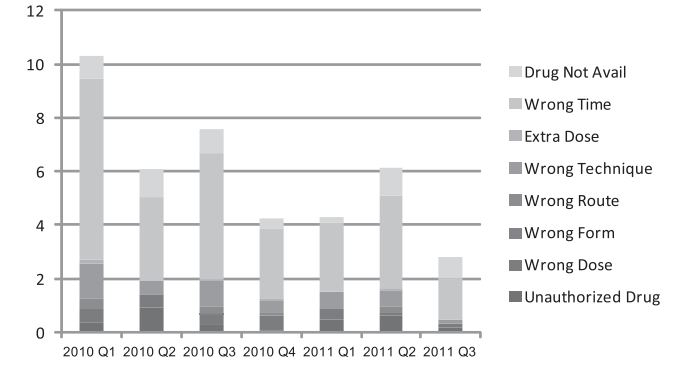

Figure 3. *Following the intervention, the total number of medication administration errors decreased from 10.3 errors/100 doses at baseline to 2.8 errors/100 doses at final follow-up (absolute risk reduction: 7.5 errors/100 doses [95% confidence interval: 5–10,* p < *.001]). At baseline, "wrong time" accounted for 86 (65%) of all 132 medication administration errors.*

"Perfect Dose" Score Reflecting the Proportion of Doses with All Six Safe Practices and No Medication Administration Errors by Quarter (*N* = 9,244 doses), January–March (Quarter 1) 2010 Through July–September (Quarter 3) 2011

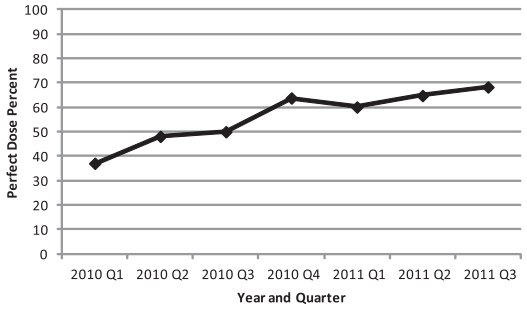

Figure 4. *The "perfect dose," reflecting compliance with all six safe practices and absence of any of the eight medication administration errors, improved from 37 in compliance/100 doses (476/1,282) at baseline to 68 in compliance/100 doses (846/1,238) at the final quarter (absolute risk reduction: 31 in compliance/100 doses [95% confidence interval: 27–35,* p < *.001]).*

andon lights) to minimize distractions, and standard work based on six safe medication administration practices. Our nurses learned that adhering to this standard work reduced rework and advanced the process of turning a medication order into a "perfect dose" for the patient.

Overall, we found the medication administration process to be amenable to both direct observation using the CALNOC study[8] and to Lean improvements. Lean requires a deep commitment to "go and see" the conditions of the shop floor, and the CALNOC study provided a strong and useful framework for this essential task. From a Lean perspective, each nurse auditor contributed to ongoing workplace inspection on his or her own unit by conducting real-time assessments. Abnormalities discovered throughout the medication administration process were shared with nursing cohorts so that countermeasures could be proposed and future errors avoided. In addition, the standard work and visual control measures that we implemented were developed by the users, a basic tenet of VMPS, which likely contributed to our success in sustaining the improvements.

Others have used observations to guide their improvement activities and measure their effectiveness in mitigating risks with the error-prone steps of the medication administration process.[6] Kliger and colleagues demonstrated the effectiveness of an Integrated Nurse Leadership Program in which front-line staff facilitated low-tech, protocol-driven changes and bedside innovations.[9,19] Although our approach to making improvements may have differed, we noted similar trends in performance as we involved our staff in Kaizen Events, created a learning infrastructure through the use of dashboards, and raised institutional awareness of the problem of medication errors. Our commitments to "go and see" and eliminate waste helped us to achieve steady gains over time.

The study setting likely had a substantial effect on the results. VMMC adopted the VMPS Lean manufacturing techniques as the institutional management approach in 2001 and has developed a strong institutional and cultural focus on QI. Implementation of our improvements was undoubtedly facilitated by staff and management's familiarity with Lean. Furthermore, this initiative was visibly supported at all times by executive leadership. We do not suggest that other institutions could adopt our interventions unaltered, but rather, that our approach, and the tools we have developed, could serve as a model for development of similarly successful interventions.

Limitations

The CALNOC observation method itself may have had an effect on the outcome through the Hawthorne effect. However, there is evidence that observation alone does not have a significant influence on error rates.[20] This report is based on a before/after comparison of outcomes in a convenience sample following a QI intervention. In the absence of a control group, we cannot determine any temporal trends that may have been

concurrent with the intervention. Most of the doses observed were given in the morning, and some nurse auditors performed fewer observations than others and may have been less adept at judging errors as they occurred. As an additional consideration, the study took place at a single institution with a strong cultural focus on quality. We are unable to determine the generalizability of our results to other settings. Nonetheless, we do demonstrate that implementation of Lean improvements in nursing medication administration is associated with substantial improvements in both the process and outcomes of care.

Conclusion

We report substantial decreases in errors in nursing medication administration with the implementation of Lean process improvements and CALNOC direct observation. Overall "perfect dose" delivery increased from 37% to 68%, and medication administration errors decreased from 10.3 to 2.8 errors/100 doses. Our results suggest that the CALNOC study supports the fundamental Lean principle of workplace inspection and that rigorous Lean QI efforts can contribute to decreasing the many injuries and deaths that occur each year from medication errors. J

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Online-Only Content

See the online version of this article for

Appendix 1. Value Stream Map of the Medication Administration Process from Medication Retrieval to Documentation as Given

Appendix 2. Redesign of the Layout of the Medication Rooms to Enable Smooth Flow of the Operator Through the Process

Appendix 3. Use of Signage to Designate the "No Talking Zone"

Appendix 4. Sample Posters Depicting Safe Medication Administration Practices

Appendix 5. Sample Dashboards, January–March (Quarter 1) 2010 Through July–September (Quarter 3) 2011

Appendix 6. Virginia Mason Medical Center's Adaptation of the CALNOC Medication Administration Accuracy Quality Study Codesheet

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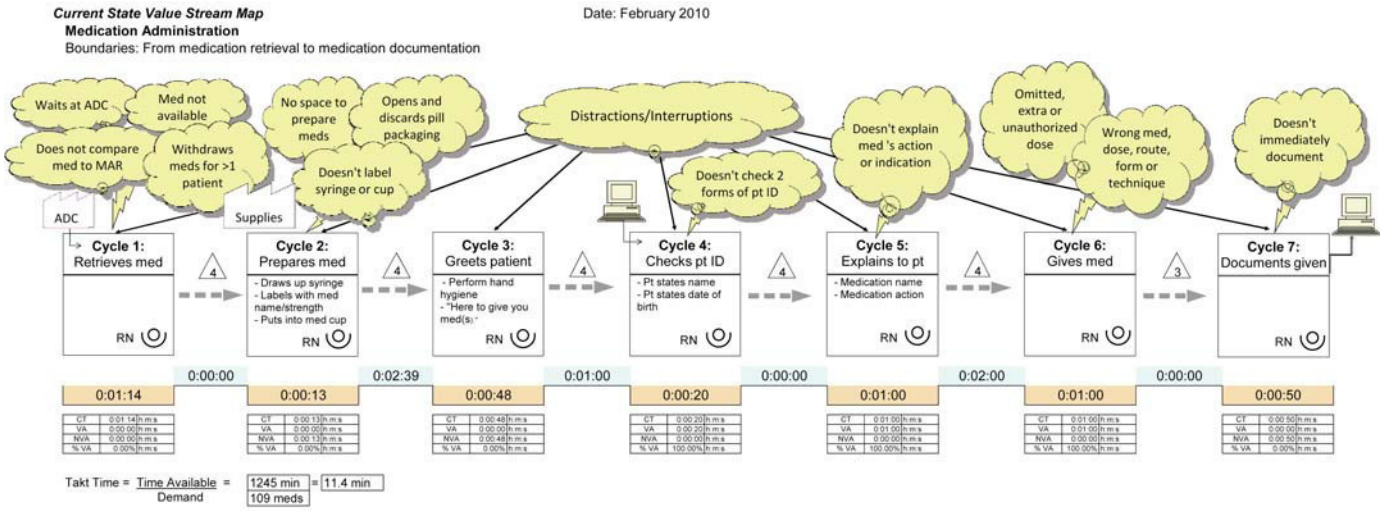
Online-Only Content

Appendix 1. Value Stream Map of the Medication Administration Process from Medication Retrieval to Documentation as Given



Nursing cycles of work are labeled 1 through 7. A cloudburst above a cycle box represents waste or inefficiency targeted for elimination in Lean process improvement events.

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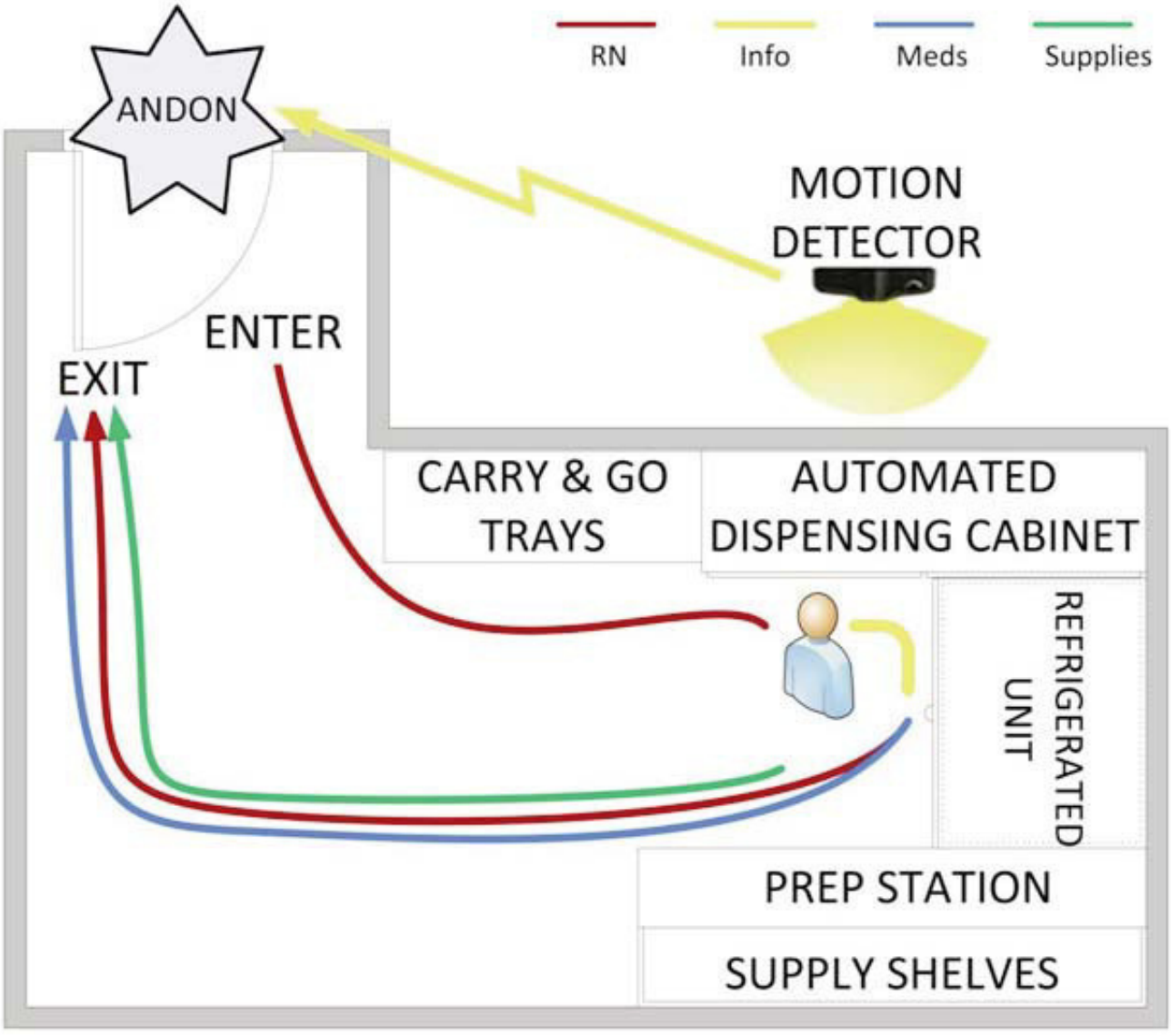
Appendix 2. Redesign of the Layout of the Medication Rooms to Enable Smooth Flow of the Operator Through the Process



All items are laid out in the order in which they will be needed. The andon warning light outside the door is triggered by a motion detector when a nurse is in front of the automatic dispensing cabinet. The colored lines represent the Flows of Medicine for the nurses, information, medications, and supplies.

Online-Only Content

Appendix 3. Use of Signage to Designate the "No Talking Zone"

The signage indicates where nurses are not to be distracted during the medication administration process. The quiet zone was also demarcated by red tape on the floor.

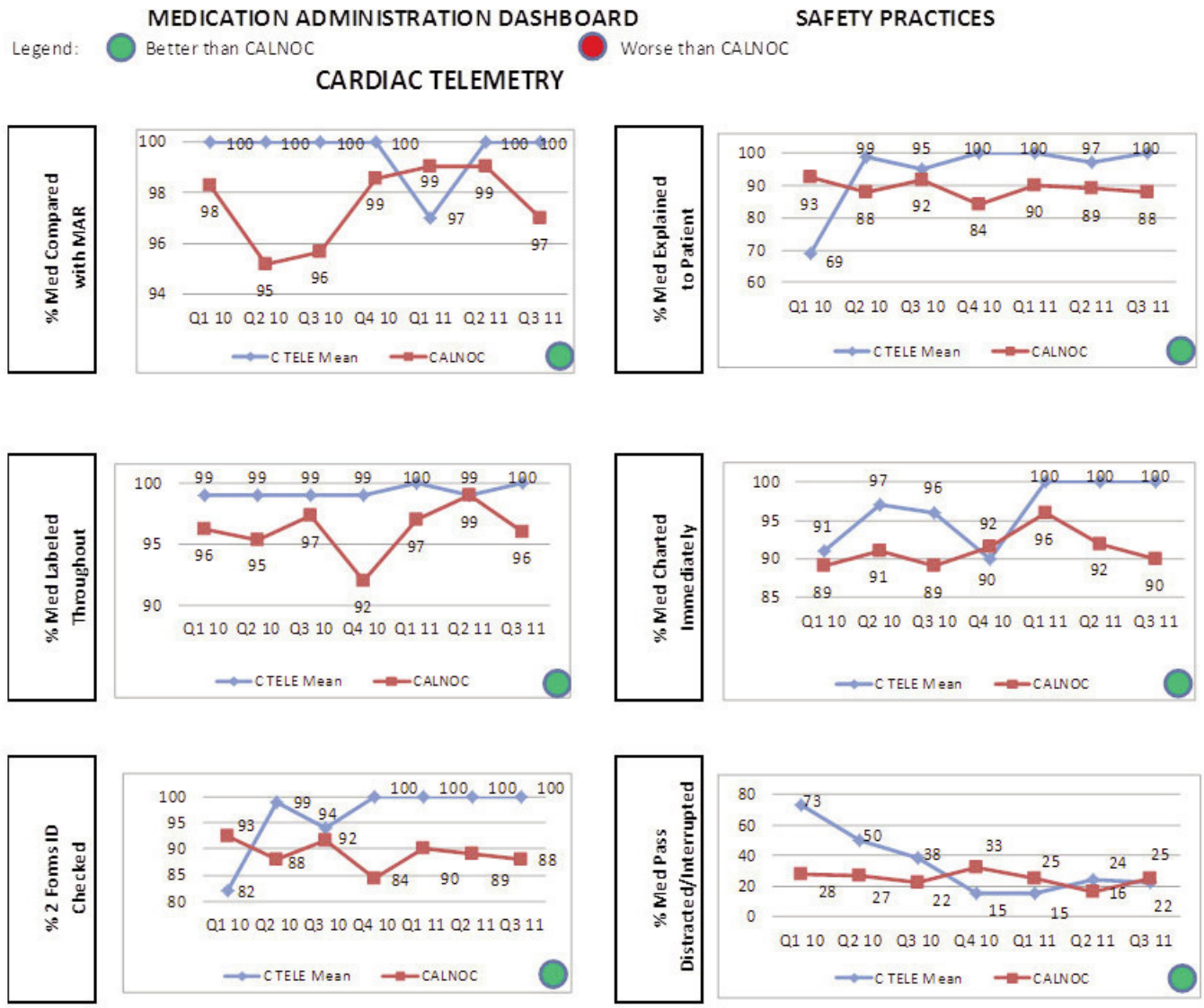
Online-Only Content

Appendix 4. Sample Posters Depicting Safe Medication Administration Practices

Standard work for the nurses during medication administration was reinforced by posters depicting the six safe practices. The common theme of "Every Patient. Every Medication. Every Time." was selected to emphasize that exceptions from the standard work are not acceptable.

Online-Only Content

Appendix 5. Sample Dashboards, January–March (Quarter 1) 2010–July–September (Quarter 3) 2011



Dashboards for each nursing unit were updated quarterly so that nurses could identify whether they were moving closer to or farther from identified targets for each of the six safe medication administration practices. C TELE, cardiac telemetry; CALNOC, mean data from multiple Collaborative Alliance for Nursing Outcomes sites; MAR, medication administration record; ID, identification. On these dashboards, performance on all measures was better than CALNOC (green dot); a red dot indicates worse than CALNOC.

Online-Only Content

Appendix 6. Virginia Mason Medical Center's Adaptation of the CALNOC Medication Administration Accuracy Quality Study Codesheet

(Patient Label)

Medication Administration Accuracy Survey

Observation Codesheet

Dose Number: _____

Number doses consecutively for each pt

Unit: _____ **Date/Time of Observation:** _____ **Reason for Admission:** ☐ Medical ☐ Surgical **Gender:** ☐ M ☐ F

Administration Observation • Answer each item for each dose • Shaded boxes indicate ERROR	**No**	**Yes**	**N/A**	**Chart Review** Compare med ordered with med administered: Code discrepancies in the "Error" column	**Error** • Complete after chart review • Mark all that apply At least one MUST be marked	**Observer Notes**
1. Compares medication with RxStation/MAR			X	Drug: _____	☐ None	
2. Medication labeled throughout process from preparation to administration			X	_____	☐ Unauthorized Drug	
3. Checks 2 forms of ID			X	Dose: _____	☐ Wrong Dose	
4. Explains medication to patient				Route: _____	☐ Wrong Form	
5. Charts medication immediately after administration			X	Form: _____	☐ Wrong Route	
6. IV infusion: Alaris Guardrails in use					☐ Wrong Technique	
7. Distraction or interruption during preparation or administration***			X		☐ Extra Dose	
					☐ Wrong Time	
					☐ Drug Not Available	

*** Distraction / Interruption Assessment (must be answered if Question #7 is marked YES)

Interruption Type (Check all that apply)	**Location / Comments**	**Self-Initiated**		**Urgent** Code, MET, Fall, etc		**Non-Urgent** ADL, pt concern, inquiries, etc.	
		No	**Yes**	**No**	**Yes**	**No**	**Yes**
( ) Non-productive talk in Med Room							
( ) Phone calls / Vocera							
( ) Nurse-to-Nurse interaction							
( ) Other discipline–to-Nurse interaction (MD, PCT etc)							
( ) Patient/family-to-Nurse interaction							
( ) Other _____							

Observer: Name: _____ **Duration of Observation** _____ Page ____ of ____ for this patient

Send Completed Codesheet to:

This adaptation captures additional elements such as use of "Guardrails" (dose-error reduction software in infusion devices) and types of distractions/interruptions.

Medication Safety

Using Lean "Automation with a Human Touch" to Improve Medication Safety: A Step Closer to the "Perfect Dose"

Joan M. Ching, RN, MN; Barbara L. Williams, PhD; Lori M. Idemoto, RPh, MS; C. Craig Blackmore, MD, MPH

Errors in medication administration harm more than 7,000 Americans per year and should be avoidable.[1] To improve the quality and safety of medication delivery, many hospitals are using machines such as bar code medication administration (BCMA) to prevent medication errors. Sixty-six percent of hospitals in the United States have already implemented some form of digital linking of medication to patient—using either radio frequency identification or electronically readable tagging bar codes as part of the Centers for Medicare & Medicaid Services electronic health record Incentive Programs ("meaningful use" of health information technology under the 2009 American Recovery and Reinvestment Act).[2] BCMA's relative effectiveness in reducing medication administration errors has been demonstrated.[3–9] On the other hand, implementing BCMA has led to unintended consequences of disrupting rather than supporting long-established nursing work flows.[10–12] Factors that lead to optimum implementation need further study.[4]

In addition to risk-mitigating technology, health care organizations have increasingly adopted Lean as a methodology to improve quality and lower costs,[13–15] and some organizations have applied it to the medication use cycle.[16] During the past 12 years, our hospital system has implemented Lean and reaped substantial gains in clinical outcomes and cost reduction.[13,17,18] We recently reported success in streamlining the work of medication administration and reducing the number of unsafe practices and errors using elementary Lean methods (such as improving the medication room layout, using visual control, and implementing nursing standard work).[19]

Despite the growing literature on Lean in health care, the Lean method of *Jidoka* has received little attention. Historically, Jidoka referred to the automatic stopping-device installed in a machine to prevent it from producing defective products.[20,21] In health care, a medication bar-code scanner is a machine with an automatic stopping device that alerts the nurse if there is a mismatch between patient, medication order, or medication itself before the nurse administers the dose. Jidoka is critical because

Article-at-a-Glance

Background: Virginia Mason Medical Center (Seattle) employed the Lean concept of *Jidoka* (automation with a human touch) to plan for and deploy bar code medication administration (BCMA) to hospitalized patients.

Methods: Integrating BCMA technology into the nursing work flow with minimal disruption was accomplished using three steps of Jidoka: (1) assigning work to humans and machines on the basis of their differing abilities, (2) adapting machines to the human work flow, and (3) monitoring the human-machine interaction. Effectiveness of BCMA to both reinforce safe administration practices and reduce medication errors was measured using the Collaborative Alliance for Nursing Outcomes (CALNOC) Medication Administration Accuracy Quality Study methodology. Trained nurses observed a total of 16,149 medication doses for 3,617 patients in a three-year period.

Results: Following BCMA implementation, the number of safe practice violations decreased from 54.8 violations/100 doses (January 2010–September 2011) to 29.0 violations/100 doses (October 2011–December 2012), resulting in an absolute risk reduction of 25.8 violations/100 doses (95% confidence interval [CI]: 23.7, 27.9, $p < .001$). The number of medication errors decreased from 5.9 errors/100 doses at baseline to 3.0 errors/100 doses after BCMA implementation (absolute risk reduction: 2.9 errors/100 doses [95% CI: 2.2, 3.6, $p < .001$]). The number of unsafe administration practices (estimate, -5.481; standard error 1.133; $p < .001$; 95% CI: -7.702, -3.260) also decreased.

Conclusion: As more hospitals respond to health information technology meaningful use incentives, thoughtful, methodical, and well-managed approaches to technology deployment are crucial. This work illustrates how Jidoka offers opportunities for a smooth transition to new technology.

errors are currently less likely to be intercepted before reaching the patient than at other phases of the medication use cycle.[22] Today, Jidoka encompasses the ways in which companies improve productivity by employing machines or "automation with a human touch."[20] Jidoka has three main components: assigning work to humans and machines based on their differing abilities, adapting machines to the human work flow, and monitoring the human-machine interaction.

In this article, we focus on the implementation of BCMA and describe how we used Lean principles of Jidoka to integrate new machines into a human work flow with minimal disruption.[20] For this investigation, we employed the Collaborative Alliance for Nursing Outcomes (CALNOC) Medication Administration Accuracy Quality Study to measure the number of unsafe administration practices and medication errors across 13 inpatient units before and after introducing BCMA machines.[23]

Methods

This project was considered to be a quality improvement effort by our Institutional Review Board, and therefore exempt from formal review.

Setting

Virginia Mason Medical Center (VMMC) is a 336-bed hospital in Seattle with 17,000 annual inpatient admissions. Participating units included 10 acute care units, ranging from 20 to 29 beds; a 33-bed ICU; an 18-bed adult rehabilitation unit; and a 17-bed emergency department. There are no pediatric or obstetrics units in our setting. Computerized provider order entry and electronic medication administration record, along with automated dispensing cabinets housed in each unit's medication supply room, have been in place on every unit since 2005. VMMC has a strong central governance structure built around the Virginia Mason Production System (VMPS), the local adoption of Lean manufacturing techniques and the Toyota Production System to health care.[13,18,20]

Planning the Intervention

Our efforts to improve medication administration safety began in 2010 with initial focus on the human work flow and culminated in full implementation of BCMA on every inpatient unit by November 2012 (Figure 1, above, right). Work-flow improvements (previously reported) consisted of measuring the current state in medication administration using the CALNOC method (specifically, six safe practices and eight error types),[23] identifying areas for improvement, applying Lean principles to reduce errors and improve flow, and measuring the results (Sidebar 1, page 343).[19] These initial work-flow interventions, undertaken before BCMA implementation, enabled us to reduce the number of observed, safe practice violations by 49% and the number of medication administration errors by 73% in a 21-month period (January 2010–September 2011). The number of perfect doses, reflecting compliance with all six safe practices and absence of any of the eight medication administration errors improved from 37% to 68%. These work-flow improvements created better flow both in the medication room and at the patient's bedside. BCMA deployment was an additional step, intended to improve medication administration even further.

Medication Administration Safety Improvements, 2010–2012

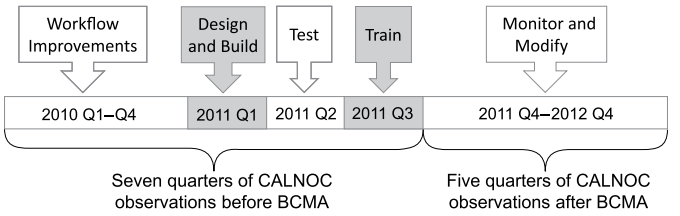


Figure 1. *During a three-year period, work-flow improvements (2010 quarters [Qs] 1–4) were followed by preparation for BCMA (2011 Q1–Q3). Nurse auditors observed administered medication doses on 13 nursing units both before and after BCMA deployment (October 25, 2011). CALNOC, Collaborative Alliance for Nursing Outcomes; BCMA, bar code medication administration.*

Leading the BCMA implementation was an interdisciplinary team that included pharmacists, clinical information specialists, and VMPS staff, as well as nurses, because adherence to standard work depends on the frontline nurse's involvement in simulation and design of the BCMA system.[24] In deploying BCMA, we set out to capitalize on the bar-code machine's strengths while keeping them in proper perspective. Nurses were reminded that BCMA is only a technical tool to help them achieve greater accuracy when administering medications. We warned nurses that BCMA would not speed up the actual process and affirmed the benefits of slowing the process down—fewer defects and less need for rework. We also took steps to safeguard the therapeutic nurse-patient relationship. Because some patients become anxious when introduced to a new electronic device, we asked a group of frontline nurses to develop a script to allay the patient's fears and to promote human touch during the scanning process (Sidebar 2, page 343).

Sidebar 1. The Collaborative Alliance for Nursing Outcomes (CALNOC) Medication Administration Accuracy Quality Study

CALNOC is a collaborative benchmarking registry targeted at nursing structural measures, care processes, and patient outcomes. The CALNOC Medication Administration Accuracy Quality Study focuses on the administration of medications by nurses to hospitalized patients. The primary outcome of the study is medication administration accuracy—that is, the administration of a medication as it was ordered. An error is a dose administered differently than ordered in the patient's chart.

Data collection in CALNOC is conducted through naïve observation:
The nurse auditor does not know the actual medications being prepared and administered but works with the observed nurse to determine the names/dosages of the medications after they are given. Compliance with six safe practices is observed and recorded:
1. Compare medication with medication administration record on removal from automatic dispensing cabinet.
2. Keep medication labeled from preparation to administration.
3. Check two forms of patient identification.
4. Explain medication to patient.
5. Chart medication immediately after administration.
6. Protect the process from distractions/interruptions.

Verification of administration accuracy is conducted through comparative record review:
The nurse auditor compares what was observed with what was ordered in the medical record to determine if there were any administration errors.
1. Unauthorized drug
2. Wrong dose
3. Wrong form
4. Wrong technique
5. Wrong route
6. Extra dose
7. Wrong time
8. Drug not available

Source: Collaborative Alliance for Nursing Outcomes (CALNOC). Medication Administration Accuracy Quality Study Definitions, Codebook_2012_Part_I. Accessed Jan 28, 2012 (available to members only). https://www.secure-calnoc.org/globalPages/mainpage.aspx.

Sidebar 2. Introducing Bar-Code Scanning Technology to Patients

In January 2011 a team of eight nurses came together to design new work flows at the bedside with BCMA technology. These team members were charged with keeping the nurse's focus on the patient and embedding the BCMA scanner into their current process. The team members started the day by learning how BCMA could reduce medication errors at the bedside. They were then given time to think about how BCMA might change their natural work flow as they acted out one scenario after another.

In addition to creating a future-state, simple medication administration process with BCMA, the team simulated nonstandard processes such as scanning and administering crushed medications and medication administration using personal protective equipment. Decisions needed to be made about documenting medications that are self-administered by the patient or accidently dropped onto the floor after scanning. Other challenges such as scanning multiuse tubes of creams and bags of total parenteral nutrition needed further problem solving with pharmacy beyond the simulation session. Session outputs such as the following scripted actions and tips were incorporated into two-hour, hands-on BCMA training for all nurses that was provided between August and October 2011, usually for 10 to 20 nurses at a time.

Scripted Actions:
- Greet the patient.
- If the patient is new to your nursing unit, point to the bar-code scanner and ask, "Have you seen this device before?"
- If the patient is unfamiliar, state, "This is a safety device that reads the bar code on your name band and brings up your medication information on my computer. I will scan the medications I've brought to you against what your doctor has ordered to make sure they're correct."

Tips:
- Include the patient throughout the scanning process and explain steps as needed to inform the patient and establish trust.
- Maintain eye contact with the patient.
- Shield the patient's eyes from scanner light with your hand.
- Keep the scanner on the vibration setting to reduce unnecessary noise.
- Always emphasize that the scanner is a safety device; the scanning has no other purpose (such as assessing a financial charge).
- Always follow required safety steps for medication administration, including high-alert medication checks.

Implementing the Intervention

The BCMA team applied the concept of Jidoka (Table 1, page 344) in three phases of machine improvement: (1) assigning work to humans and machines on the basis of their differing abilities, (2) adapting machines to the human work flow, and (3) monitoring the human-machine interaction.

1. Assigning Work by Abilities. We began our work by determining what humans and machines do best (Table 2, page 344) and how bar-code technology, acting as extensions of one's hands and feet, could complement the skills of our care providers.[20,21,24] Humans excel at tasks requiring cognitive flexibility and customer interactions. Machines, on the other hand, excel at tasks that are repeatable, narrow, and specific. The Lean Jidoka approach combines the individual strengths of nurse and machine in the medication administration process. The nurse interacts with the patient in a caring and supportive manner. The BCMA system, on the other hand, provides the repetitive series of safety checks needed to prevent errors by interfacing with both pharmacy and provider order entry systems. As the nurse scans the bar codes on the patient's wristband and individual medication packages, the machine verifies patient identity, medication identity, dose, dosing units, dosage form, route,

Table 1. Lean Concepts

Lean Concept	Definition	Medication Administration Example
Jidoka	Building in quality, intelligent automation with defect prevention strategies	BCMA system checks for any discrepancy between patient, medication order, and dose to be administered.
Andon	Visual control system that reflects the status of the process or worker	Bar-code scanner alerts nurse.
VMPS Flows of Medicine	Fundamental components of any process that flow together to create the patient's experience: (1) patients, (2) providers, (3) family and relationships, (4) medications, (5) supplies, (6) equipment, (7) information, and (8) process engineering	The flow of nurses, medications, supplies, and equipment within the patient's room
Standard Work	Sequencing of steps within a process that is repeatable by all who perform the work	Six safe medication administrative practices; scanning bar codes on patient wristband and medication packaging
Management by Sight	A visual control system that brings production weaknesses to the surface so actions can be taken to prevent further defects	Biweekly reports of nursing unit compliance with scanning patient wristbands and medication

BCMA, bar code medication administration; VMPS, Virginia Mason Production System.

and administration time. The nurse reviews the transaction in the BCMA system and accepts it with one keystroke, completing the documentation process.

2. Adapting Machines to the Human Work Flow. Under Jidoka, after assigning work by abilities, our second task was to adapt the machine to fit into the human work flow without disruption. As described earlier, before BCMA implementation we had performed the foundational work of improving the human work flow. A key component of integrating BCMA into the human work flow was device selection, so we held a bar-code technology device fair in January 2011 and encouraged nurses to "test-drive" numerous handheld scanners. Feedback on the following handheld scanner attributes was obtained: dimensions, remote ability, ease of scanning, ease of cleaning, and durability; the two most popular features were Bluetooth functionality and multisensory, user feedback (the device vibrates, audibly chirps, and visually flashes).

Table 2. Humans vs. Machines: What They Do Best

Humans Excel	Machines Excel
Flexibility	Repetitive tasks
Evaluating subjective criteria	Tasks that require little/no subjective judgment
Interacting with customers	Mathematical calculations Extremely fine measurements

It then took us almost one year to understand how the BCMA system actually functioned and what staff needed at each point in the process to successfully "build" a perfect dose without any wasted motion. During this time, we made software and device decisions regarding the interface appearance to the user, the types of warnings the user would see, and how the software would allow the user to interact with these warnings. For example, we could have employed "hard stops" in the BCMA system that would *not* have allowed the nurse to proceed when a mismatch between patient, medication, or order was detected. We instead opted for a warning to prompt the nurse to investigate the reason for the warning and decide whether or not to proceed with medication administration. Adapting the machine to the nurse meant building in flexibility, a key principle of Jidoka.

Fitting a machine into a human work flow led us to apply the VMPS Flows of Medicine (as described previously)[19] in patient rooms as nurses administered medications. A team of nurses and pharmacists observed and mapped on paper the movements of nurses, medications, supplies, equipment, and information at baseline, and with simulation of BCMA use. The VMPS Flows of Medicine* exercise revealed how much BCMA could disrupt existing work flows[10,11]; for example, some nurses had to walk back to the medication room to obtain new doses of medication after realizing they could not scan the medication bar-code label because it had been torn in the process of opening the packaging. Also, we saw a nurse leave the patient's bedside in the middle of scanning medications to consult with a pharmacist. Both nurse and pharmacist were puzzled why the bar code on a medication ordered for the patient could not be scanned.

Simulation taught us that the BCMA system lacked the flexibility of the human-driven system and would be effective only if two key conditions were met. First, the information necessary to carry out the task must be in a form that the BCMA machine understands. That meant that a correct bar code needed to be on every dispensed medication and every patient wristband.[25]

* Use of the VMPS Flows of Medicine involved a team's tracking and recording on a graphic representation of the work area the process (or flow) for each of the important components of medical care: patients, providers, family and relationships, medications, supplies, equipment, information, and process engineering.

Example of Selection of Which Bar Code to Scan When a Medication Has Multiple Bar Codes

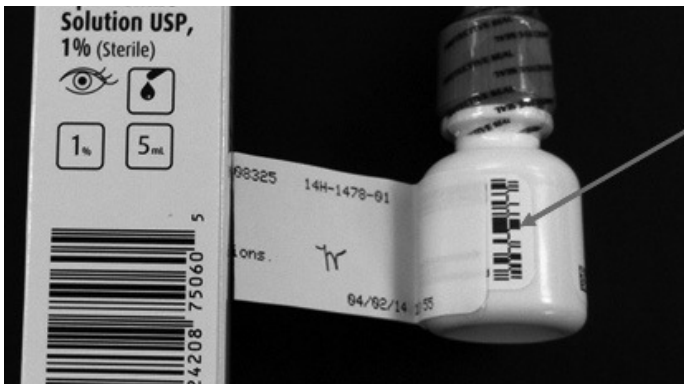


Figure 2. *Pharmacists and nurses agreed on which bar code would be scanned for medications with multiple bar codes: the bar code on the actual product (arrow),* not *on the package or overwrap. The box in the example above can be easily discarded, whereas the bar code on the bottle is at point-of-use. (Available in color in online article.)*

The second key condition was standardizing the process into a series of rules to cover all clinical situations. For example, pharmacists and nurses needed to agree on which bar code should be scanned for medications with multiple bar codes—we selected the bar code closest to the actual product, not on the package or overwrap. In one case, a multidose bottle of eyedrops has both a bar code on the cardboard box in which it is dispensed, as well as on the bottle itself. Because the box can become separated from the bottle and discarded, nurses needed the "true" bar code on the medication vehicle itself so it could be scanned at the point of administration (Figure 2, above).

We also had to develop rules for nurse-prepared medications such as insulin drawn out of a multidose vial and for nonstandard doses (for example, ½ tablets). When practice substantially varied from nurse to nurse or unit to unit, rule-writing was particularly challenging; for example, as with medications that need to be crushed and diluted before administration. However, through simulation and small tests of change, the team achieved consensus and incorporated these types of scenarios into our two-hour nurse training class that was required before using the BCMA system.

3. Monitoring the Human-Machine Interaction. The final component of Jidoka recognizes that introducing a machine like BCMA is not a one-time initiative. It is rather an iterative process that requires ongoing modifications and improvements.[4,12] We anticipated that users would encounter barriers and that they might circumvent the BCMA system. Thus, we used its software to display compliance with scanning patient wristbands and medications generated at every user level: system, nursing unit, and individual nurse. Together with direct medication administration observations, these biweekly reports became part of our "management-by-sight" surveillance (Table 1) and were useful in detecting workarounds and system-related issues.[3] When monitoring revealed a less-than-desired performance, we asked if the noncompliance could be attributed to the user (for example, lack of understanding), the process (procedural or training deficiency), or the system (product purchasing decision or manufacturer error). We could then focus our improvement efforts and evaluate their impact on the human-machine interaction.

Evaluating the Intervention

Study Design. To evaluate the effectiveness of using Jidoka principles when implementing BCMA, we performed a cohort study in which safe practice violation and medication error rates were compared during a three-year period encompassing BCMA adoption. In addition, we performed an interrupted time series analysis on a subset of practice violations and medication errors targeted by the BCMA system.[3] The study was based on prospectively collected data using the CALNOC Medication Administration Accuracy Quality Study.[23]

Outcome Measures. The primary outcome was the numbers of safe practice violations and errors in medication administration, determined from CALNOC observations. We were concerned enough about disrupting the human work flow that, as a secondary analysis, we assessed compliance with BCMA scanning immediately following its introduction and during the subsequent five quarters for all medication administration events on the same units.

Data Analysis. We included medication administration on patients ≥ 18 years of age who were hospitalized between January 2010 and December 2012. The current study, a continuation of our original study,[19] which began in January 2010, compares a period when the majority of human work-flow improvements were implemented on all units to post-BCMA adoption (Figure 1). The analysis for the primary outcome of safe practice violations and medication errors was based on a before-and-after comparison of simple means for the seven quarters before the intervention (January 2010–September 2011) and the five quarters following the intervention (October 2011–December 2012). Quarterly observations consisted of a convenience sample of 100 doses per nursing unit (as defined by CALNOC)[23] collected by trained nurse observers.

Means for all types of errors before the intervention were

Safe Practice Violations per 100 Doses by Quarter, Before and After Implementation of Bar Code Medication Administration, January 2010–December 2012

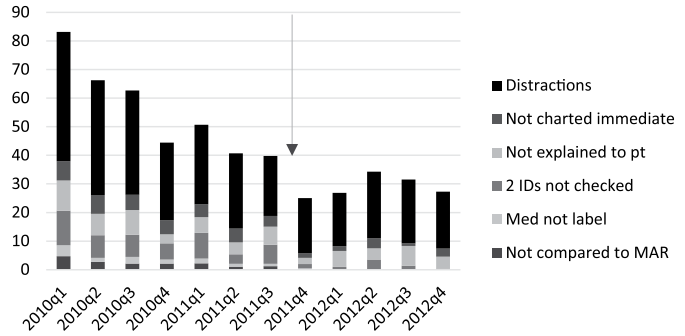


Figure 3. *Following implementation of bar code medication administration (arrow), the number of safe practice violations decreased from 54.8 violations/100 doses (January 2010–September 2011) to 29.0 violations/100 doses (October 2011–December 2012), resulting in an absolute risk reduction of 25.8 violations/100 doses (95% confidence interval: 23.7, 27.9,* p < *.001). The greatest percentage of change occurred with not checking two forms of patient identification (from 7.4 per 100 doses to only 1.5 per 100 doses). Q, quarter; pt, patient; IDs, identifiers, MAR, medication administration record. (Available in color in online article.)*

Medication Error Types per 100 Doses by Quarter, Before and After Implementation of Bar Code Medication Administration, January 2010–December 2012

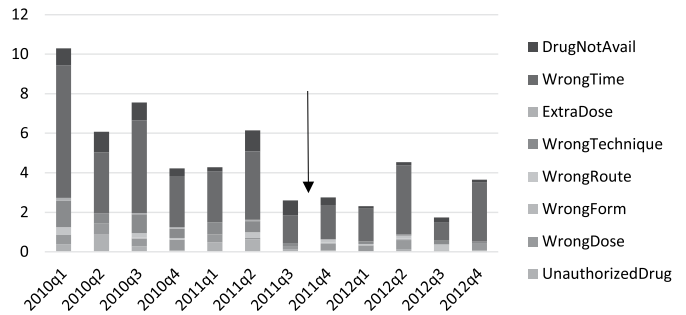


Figure 4. *Following implementation of bar code medication administration (arrow), the number of medication errors decreased from 5.9 errors/100 doses (January 2010–September 2011) to 3.0 errors/100 doses (October 2011–December 2012), resulting in an absolute risk reduction of 2.9 errors/100 doses (95% confidence interval: 2.2, 3.6,* p < *.001). There was a significant reduction (*p < *.001) in four (unauthorized drug, wrong technique, wrong time, and drug not available) of the eight types of medication administration errors. Q, quarter. (Available in color in online article.)*

compared with the time period after the intervention using *t*-tests, and cross-tabulations were analyzed with chi-square. Changes over time were assessed using linear regression. Stata 12 (StataCorp, College Station, Texas) was used for all statistical tests.

We used segmented time series regression analysis to assess BCMA's impact on three safe practices automated by the BCMA system and four error types prevented by the BCMA system. The target safe practices were medication labeled from preparation to administration, two forms of patient identification checked, and medication charted immediately after administration. The target errors were unauthorized drug, wrong dose, wrong form, and extra dose. After BCMA implementation, we also used the computer system's log of scanned activity to calculate the percentage of scanning compliance for both patient wristbands and medication bar codes out of all medication administration events.

Results

Patients

Trained nurses observed a total of 16,149 medication doses given to 3,617 unique patients during the study period (January 2010–December 2012).The mean age for these patients was 64 years (range, 18–110), and 54% of them were women. The mean number of doses per patient was 3.8 (SD [standard deviation] = 3.2; range, 1–23).

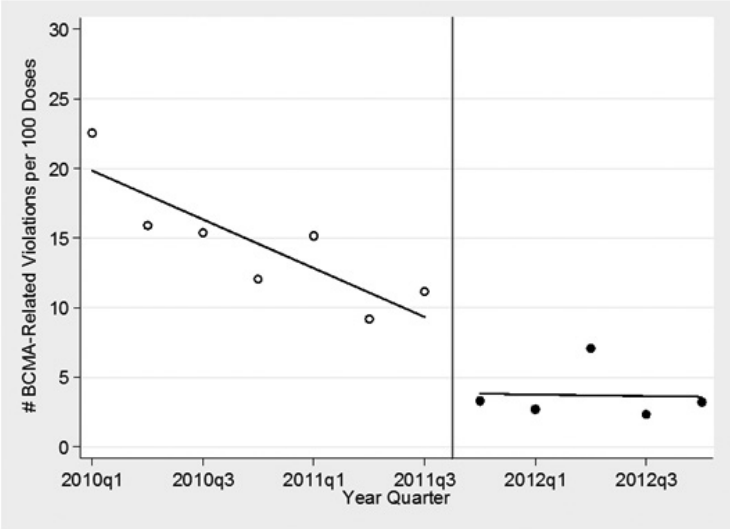
Safe Practice Violations

The most common CALNOC safe practice violations throughout the observation period were distractions/interruptions (27.0 per 100 doses, 4,357/16,149) and not explaining the medication to the patient (5.7 per 100 doses, 922/16,149). As shown in Figure 3 (above, left), the number of safe practice violations decreased from 54.8 violations/100 doses before BCMA implementation (SD = 77.0, *N* = 9,353 doses) from January 2010 through September 2011 to 29.0 violations/100 doses after BCMA implementation (SD = 51.7, *N* = 6,796 doses) from October 2011 through December 2012 (absolute risk reduction: 25.8 violations/100 doses [95% CI [confidence interval]: 23.7, 27.9, $p < .001$]). When comparing violations before the intervention with the five quarters following the intervention, there was a significant reduction ($p < .01$) in each of the six types of violations, with the greatest percentage of change in not checking two forms of patient identification—from 7.4 per 100 doses to only 1.5 per 100 doses. Automating the administration process reduced the opportunity for practice variation and reinforced three of six safe practices, particularly checking two forms of patient identification.

Medication Administration Errors

The most common CALNOC medication administration errors throughout the observation period were wrong time (3.0 per 100 doses, 479/16,149) and the medication not being available (0.5 per 100 doses, 82/16,149). Figure 4 (page 346) shows the number of medication administration errors by quarter. Following BCMA implementation, the number of medication errors decreased from 5.9 errors/100 doses (SD = 25.5, N = 9,353 doses) from January 2010 through September 2011 to 3.0 errors/100 doses (SD = 18.2, N = 6,796 doses) from October 2011 through December 2012 (absolute risk reduction: 2.9 errors/100 doses [95% CI: 2.2, 3.6, $p < .001$]). Comparison of the seven quarters before the intervention with the five quarters following the intervention revealed a significant reduction ($p < .001$) in four (unauthorized drug, wrong technique, wrong time, and drug not available) of the eight types of medication administration errors, with the greatest percentage of improvement in wrong technique, from 0.7 per 100 doses to only 0.1 per 100 doses. There was no significant trend in administration errors independent of the BCMA intervention identified in the regression analysis.

Bar Code Medication Administration Target Violations, First Quarter (Q) 2010–Fourth Quarter 2012



Variable	Parameter Estimate	Standard Error	t Value	Approx Pr > |t|
Time	-1.750584	0.1763845	-9.92	< .001
Intervention	-5.480553	1.133086	-4.84	< .001
Time after	1.701541	0.3380817	5.03	< .001

Figure 5. *Target practice violations steeply decreased during the work-flow improvement period (2010 Q1–2011 Q3) and decreased further (5.5 violations/100 doses,* p < *.001) following implementation of bar code medication administration (October 25, 2011) and remained consistently low during five quarters (2011 Q4–2012 Q4).*

Impact of Bar Code Medication Administration on Target Violations and Medication Errors

We used segmented time series regression analysis to assess the impact of BCMA on three targeted practice violations and four error types. Target practice violations outnumbered medication errors throughout the observation period and showed a steeper decline during the work-flow improvement period.[19] The number of BCMA target violations decreased further by 5.5 violations (Estimate, -5.481; standard error [SE] 1.133; $p < .001$; 95% CI: -7.702, -3.260) following BCMA implementation and remained consistently low over five quarters (Figure 5, right). Conversely, medication errors deemed preventable by a BCMA system were few in number (mean 0.8 errors/100 doses before, 0.4 errors/100 doses after) and showed a steady decline throughout the observation period. No change in slope or number of errors was observed following BCMA implementation (Quarter [Q] 4 2011–Q4 2012, t = -0.06, p = .95) (Figure 6, page 348).

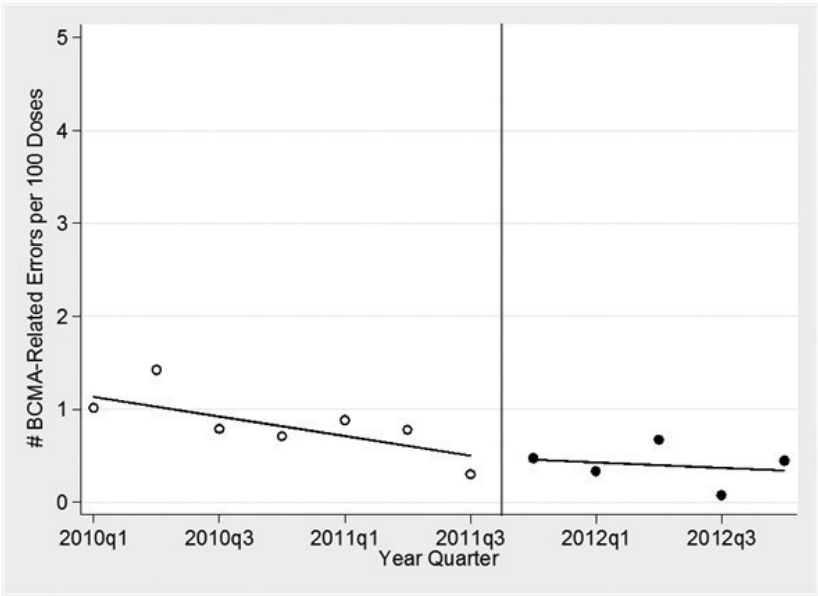
Compliance with Bar-Code Scanning

The patient wristband was scanned 90.8% (1,800,146/1,981,982) of the time following BCMA implementation, and the medication was scanned 87.9% of the time (1,742,188/1,981,982). Situations in which patients were not scanned included patient self-administered medications or when the patient's wristband was not accessible (for example, under sterile drape). Situations in which the nurse was not able to scan medications included medications given during emergencies and bar codes that were unreadable, though these were not measured individually.

Discussion

In this article, we describe the application of the Lean concept of Jidoka to improve the safe delivery of medications to hospitalized patients in the context of BCMA implementation. Jidoka allowed us to optimize the use of the BCMA technology, while maintaining the preferred human work flow, leading to decreases in both the number of safe practice violations and

Bar Code Medication Administration–Related Errors per 100 Doses, First Quarter (Q) 2010–Fourth Quarter 2012



Variable	Parameter Estimate	Standard Error	*t* Value	Approx Pr > |t|
Time	-0.1050331	0.0420132	-2.50	0.012
Intervention	-0.0159885	0.2698906	-0.06	0.953
Time after	0.0761262	0.080528	0.95	0.345

Figure 6. *Medication errors deemed preventable by a bar code medication administration system were few in number (mean 0.8 errors/100 doses before, 0.4 errors/100 doses after) and showed a steady decline throughout the observation period. No change in slope or number of errors was observed following implementation (2011 Q4–2012 Q4,* t = *-0.06,* p = *.95).*

medication administration errors. Taking advantage of the relative strengths of both humans and machines and monitoring their interaction enabled quicker adoption and long-term sustainability.[10]

We began our work with the first step of Jidoka by determining what humans and machines do best. Nurses are undoubtedly better suited than machines to detect subtleties in patient behavior and respond promptly and accordingly. Similarly, patients who face health crises may seek the therapeutic nurse-patient relationship over a machine interface. Machines, on the other hand, outperform nurses in tasks requiring detailed checking or flawless execution of standard processes (for example, confirming the right patient, medication, dose, route, and time). Unlike humans, machines are not susceptible to fatigue or environmental stressors such as noise or poor lighting, so tasks that are repetitive, detailed, and time-consuming are more likely to be completed.

The second step of Jidoka consists of adapting machines to a human process. Although BCMA systems have been in use as a patient safety tool since 1999,[26] no system comes off-the-shelf and ready for use. BCMA technology must be adapted to the unique features and work flow of each hospital if it is to be effective.[11] More difficult to predict is the magnitude of adaptation that both machine and human must undergo to support the current work flow. For example, we discovered that the BCMA interface sold and supported by our own EHR vendor neither resembled the electronic medication administration record to which nurses were accustomed nor shared the same safety features. Because we could not modify the BCMA display, we needed to create nursing work that compensated for this perceived shortcoming.

Nurses may not mind the few additional steps necessary to achieve perfectly administered doses with BCMA. However, if nurses perceive the BCMA system as overly cumbersome, inflexible, or inefficient, they can devise workarounds to compensate for system flaws and inconvenience[11,12] paradoxically leading to new errors. Thus, our solution focused on involving nurses in creating standard work procedures. The high rates of nursing compliance with scanning both patient wristbands and medications were interpreted as their approval of the new machine in their work flow.

Although we made it as easy as possible to comply with standard work, we made it nearly impossible to work around patient scanning. Others have reported a common shortcut of printing and scanning patient-specific bar-code labels rather than scanning the patient's actual wristband before medication delivery.[11] While conceived as a time- or energy-saving effort, this shortcut can result in medication administration errors. Thus, we intentionally made it difficult to print more than one bar-coded wristband per patient at the point of admission and eliminated all computer-generated patient bar-code printing on nursing units.[25] If a patient's wristband was damaged, removed, or unable to be scanned during hospitalization, staff followed a standard process for wristband replacement involving our Admitting Department. If a medication needed to be given right away, and the patient's wristband was missing or not

Table 3. Four Levels of Automation

Level	Definition	Medication Administration Example
1. Manual labor	Worker performs all of the labor.	Nurse administers IV bolus medication.
2. Mechanization	Worker and machine share the labor.	Nurse administers IV medication via gravity flow.
3. Automation	Machine takes over the labor so the worker can step away.	Nurse administers IV medication via infusion device with dose-error reduction software.
4. Autonomation (Automation with defect prevention)	Machine performs all the labor, stops for defects, and requires no human supervision.	Fully integrated electronic system: infusion device with dose-error reduction software and EHR

IV, intravenous; EHR, electronic health record.

able to be scanned, the nurse established the patient's identity and checked the medication details against the order before administering the medication. Regular reviews of electronic logs for excessive wristband printing activity could be used to detect at-risk behavior.

Because defect-free production relies on high-quality interactions between humans and machines, the third step of Jidoka consists of monitoring those interactions. An ideal BCMA system balances the work between nurse and machine so confirmation of medication accuracy flows with little effort, and the synergy between the two is reflected by the absence of practice violations or actual errors. Had we not employed direct observation as we did, we would have needed more actionable reports of nurse-machine interactions than the BCMA's default reports. Hospitals may benefit by investing in tailored BCMA reports to address their particular risks and practice concerns.

Our overall results also demonstrate the advantages of addressing human work-flow improvements before employing new machines. We suspect that the BCMA system reinforced nursing standard work—as a product of initial work-flow improvements—and even fortified such practices as verifying two forms of patient identification, supporting the Joint Commission's National Patient Safety Goal on confirming patient identity.[27†] Automating these safe practices ensures sustainability over time.

Finally, we are in an elementary stage of Jidoka as compared to the advanced use of machines in manufacturing. BCMA's dependence on both nursing presence and judgment limits Jidoka's true ability to error-proof medication administration and to reduce the number of staff needed to care for a patient. Unlike the bar-code scanner, "autonomous" machines in manufacturing are not dependent on human beings to stand by and intervene if abnormalities arise (Table 3, left). As a result, manufacturers are able to attend to more than one machine at a time and maximize production efficiencies. In fact, the ideal, autonomous machine requires no worker at all.[20] While we are far away from using autonomous machines in patient care today, the bar-code scanner's autonomous-like property creates additional capacity for nurses to attend to other important considerations and to be more fully present for patients. Nurses report that the bar-code scanner provides a "safety net" and rationalizes the number and types of checks to ensure that the perfect dose reaches the patient.

† NPSG.01.01.01: Use at least two patient identifiers when providing care, treatment, and services.

Limitations

Limitations to this study include those associated with direct observation and the possibility of the Hawthorne effect. However, there is evidence of a negligible effect on the observed nurse if the observers are experienced and unobtrusive.[28] The study's cohort of nurse observers remained relatively stable over the three-year data collection period, and any effect would have likely impacted both before- and after-observation periods equally. One limitation is the lack of a suitable control group, as all nursing units were converted at the same time to the BCMA system. The study was conducted at a single hospital with fully implemented computer provider order entry and bar-code verification systems for pharmacy staff. We cannot determine applicability to other institutions that have different processes for medication delivery, utilize other forms of technology to prevent medication errors, or have different staffing models.

Conclusion

In this report we detail the development and implementation of medication bar-code scanning using the Lean principle of Jidoka to decrease administration errors in the hospital setting. We report increased compliance with safe medication administration practices and a decrease in the number of observed medication errors. As more hospitals respond to meaningful use incentives, thoughtful, methodical, and well-managed approaches to technology deployment are crucial. Our institution has opted to use Lean methodologies toward the goal of improving patient outcomes, and this example illustrates how Jidoka offers opportunities for a smooth transition to new technology. J

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Figure 2. Example of Selection of Which Bar Code to Scan When a Medication Has Multiple Bar Codes (color version)

Figure 3. Safe Practice Violations per 100 Doses by Quarter, Before and After Implementation of Bar Code Medication Administration, January 2010–December 2012 (color version)

Figure 4. Medication Error Types per 100 Doses by Quarterw, Before and After Implementation of Bar Code Medication Administration, January 2010–December 2012 (color version)

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Figure 2. Example of Selection of Which Bar Code to Scan When a Medication Has Multiple Bar Codes

Pharmacists and nurses agreed on which bar code would be scanned for medications with multiple bar codes: the bar code on the actual product (red arrow), not on the package or overwrap. The box in the example above can be easily discarded, whereas the bar code on the bottle is at point-of-use.

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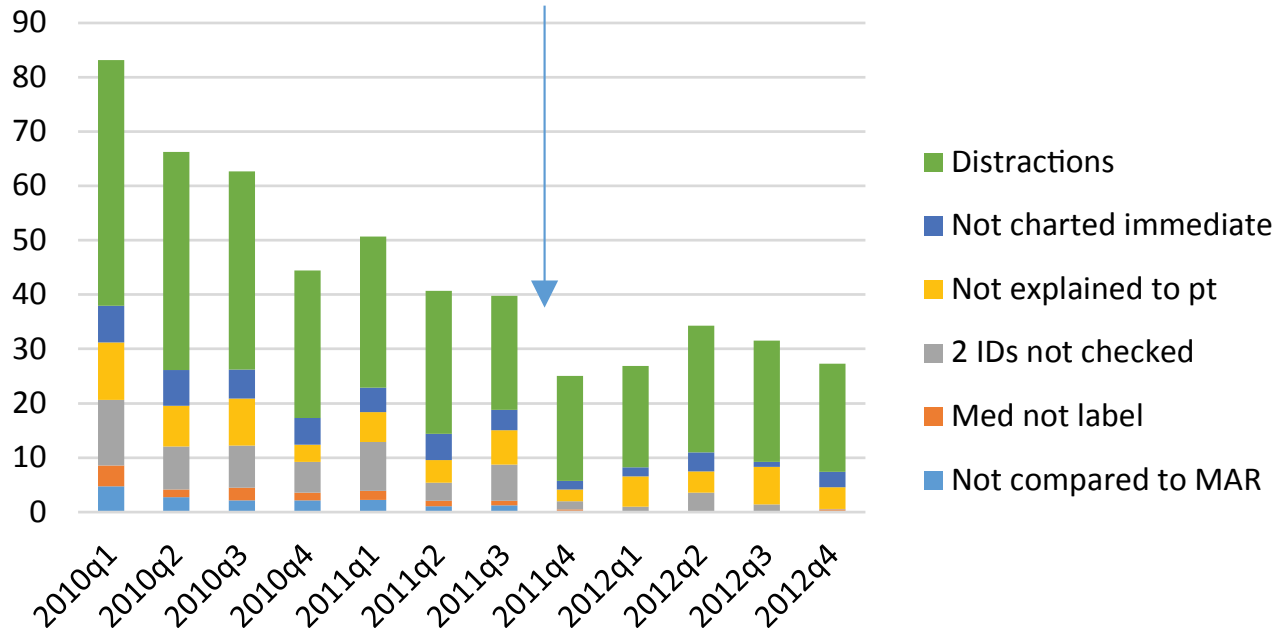
Figure 3. Safe Practice Violations per 100 Doses by Quarter, Before and After Implementation of Bar Code Medication Administration, January 2010–December 2012



Following implementation of bar code medication administration (blue arrow), the number of safe practice violations decreased from 54.8 violations/100 doses (January 2010–September 2011) to 29.0 violations/100 doses (October 2011–December 2012), resulting in an absolute risk reduction of 25.8 violations/100 doses (95% confidence interval: 23.7, 27.9, $p < .001$*). The greatest percentage of change occurred with not checking two forms of patient identification (from 7.4 per 100 doses to only 1.5 per 100 doses). Q, quarter, pt, patient; IDs, identifiers, MAR, medication administration record.*

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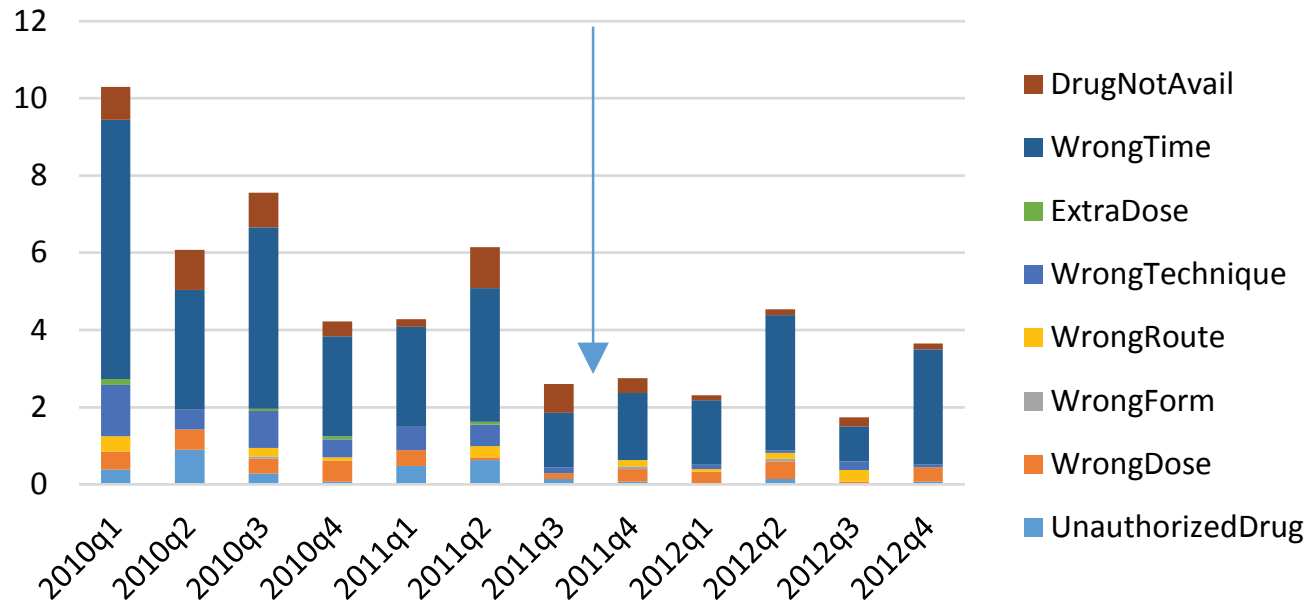
Figure 4. Medication Error Types per 100 Doses by Quarter, Before and After Implementation of Bar Code Medication Administration, January 2010–December 2012



Following implementation of bar code medication administration (blue arrow), the number of medication errors decreased from 5.9 errors/100 doses (January 2010–September 2011) to 3.0 errors/100 doses (October 2011–December 2012), resulting in an absolute risk reduction of 2.9 errors/100 doses (95% confidence interval: 2.2, 3.6, $p < .001$*). There was a significant reduction (*$p < .001$*) in four (unauthorized drug, wrong technique, wrong time, and drug not available) of the eight types of medication administration errors. Q, quarter*

An Evaluation of a Collaborative, Safety Focused, Nurse-Pharmacist Intervention for Improving the Accuracy of the Medication History

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Objective: To evaluate the impact of a standardized approach to collecting a medication history on the accuracy of the admission medication list.

Methods: Pharmacists and nurses developed and implemented a structured, systematic assessment tool for use by nurses in obtaining a medication history. The tool was first evaluated with nursing students in an educational setting using mock patients and simulated scenarios. The number and type of medication errors (omissions) were compared between controls and those using the tool. Based on the findings from this phase of the study, we refined the tool and then implemented it on four medical/surgical units in a large academic teaching hospital and a smaller, affiliated community hospital. We compared medication error rates using hospital safety report records and discrepancies (i.e., delays in ordering, omissions) before and after implementation of the tool.

Results: Accuracy of the medication history improved significantly with student nurses who used the tool versus those who did not (87% versus 74%, $P = 0.010$). We were unable to evaluate the numbers of medication discrepancies in the academic medical center because of a lack of availability of electronic admission history and physical reports during the study period. At the community hospital, there was a significant increase in the percentage of patients without medication discrepancies (before = 20% versus after = 42%, $P = 0.017$), a significant reduction of minor medication omissions during the hospital stay (1.10 versus post 0.60, $P = 0.003$) and a trend toward the reduction of important drug omissions in the discharge summary (pre 0.43 [0.71] versus post 0.18 [0.44], $P = 0.053$). The most common agents involved in a delay or omission were multivitamins, laxatives, antidepressants, antidiabetic agents, platelet inhibitors, and acid-suppressing agents.

Conclusions: The use of a structured tool to systematically obtain a medication history produced a measurable improvement in the accuracy of the admission medication list by student nurses and a reduction of medication errors in a community hospital.

Key Words: medication history, nurse-pharmacist collaboration, medication assessment

(*J Patient Saf* 2014;10: 88–94)

Nurses play a critical role in ensuring that patients receive the correct medications in the inpatient setting. Medication errors are common and present serious patient safety risks.[1–3] The nurse's ability to collect a complete and accurate medication list on admission can impact patient safety throughout the hospital stay and into the postdischarge period. Little is known about optimal methods of ensuring that this process is carried out efficiently and effectively. This study was conducted to test the effect of a structured, systematic approach on accuracy of the medication history and frequency of medication errors.

PURPOSE/SPECIFIC AIMS

Specific aim 1—To evaluate the effectiveness of a structured, systematic medication history-taking tool on the accuracy of the medication list obtained by student nurses.

Specific aim 2—To evaluate the effectiveness of a structured, systematic medication history-taking tool on the frequency of medication errors in the medical-surgical inpatient setting.

Specific aim 3—To evaluate staff nurse satisfaction with, and recommendations for, improvement in a new medication history-taking tool.

REVIEW OF THE LITERATURE AND SIGNIFICANCE

The importance of obtaining and documenting an accurate medication history is receiving increased attention, as more studies point to the high number of medication errors that occur in hospitals.[1–3] Several innovations have been attempted to decrease medication errors in the hospital including medication reconciliation.[4–9] Medication reconciliation has been shown to be useful in reducing some medication errors but still relies heavily on the collection and documentation of an initial medication history to be effective.

Ensuring that patients receive the correct medications throughout the inpatient stay should be a collaborative and ongoing effort between patients, family members, and health-care providers. In many instances, a nurse is the first health professional to initiate the medication history process, making it imperative that he or she be able to do so both effectively and efficiently.[10]

Medication histories are often incomplete or inaccurate[3,11–14] Although research supports the need to obtain complete and accurate medication histories on admission,[5,6] this has proven to be difficult as studies have shown that up to two thirds of medication histories have errors.[3,11–18] Although research supports the ability of pharmacists to collect comprehensive and accurate histories,[11,13–15] there has not been a similar focus on nurses despite the fact they often collect the initial admission medication history.[19,20] There has also been little research on how the education of new nurses or the continuing educational development of nurses in practice affects the assessment of a patient's medication history or medication safety in general.[21]

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THEORETICAL FRAMEWORK

The modified Eindhoven model, adapted for nursing error recovery served as the theoretical framework for the study.[22] This model describes how organizational, technical, and human failures can lead to dangerous situations that ultimately may negatively affect the patient. Structures and processes adopted by the organization, such as a systematic method for collecting and recording the medication history, are examples of mechanisms that have the potential to significantly decrease negative patient outcomes.

DEFINITIONS

Reported medication error—A medication error reported by nurses, physicians, or pharmacists using the hospital's patient safety reporting system (an anonymous, self-report system).

Discrepancy—A discrepancy between the patient's admission, inpatient, and discharge record not otherwise indicated by a change in the patient's medication needs as determined by a panel of expert advanced practice nurses and pharmacists.

Delay—A delay in ordering a patient's usual medication not otherwise indicated by a change in the patient's medication needs as determined by a panel of expert advanced practice nurses and pharmacists.

Omission—The failure to order a patient's usual medication not otherwise indicated by a change in the patient's medication needs as determined by a panel of expert advanced practice nurses and pharmacists.

Minor or important omission or delay—Significance of the medication omission as determined by a panel of expert advanced practice nurses and pharmacists.

Reconciliation accuracy—The percentage of medications identified by the student nurses from the total number of medications on the mock patient's complete medication list.

METHODS

A new tool was created to facilitate a systematic approach to collecting a medication history. This tool was developed and refined by a cohort of clinical nurses, nurse educators, and clinical pharmacists with expertise in patient safety that practice in academic and clinical settings. The rationale and process for developing the tool has been described elsewhere in detail.[10] Briefly, the tool provides a structured, systematic process for collecting a medication history, which is used by the nurse as part of the initial admission assessment (Fig. 1). The tool includes asking the patient for sources of medication data to "build the list" (e.g., medication bottles, medication lists) and a head-to-toe approach to "cue" patients to both medications and health problems requiring medication therapy. The tool and approach were evaluated initially with nursing students and later in an inpatient clinical setting. Institutional review board approval was obtained before the start of the study.

Procedure/Data Collection

Specific Aim 1

Undergraduate student nurses were randomized to either the intervention group (education and training in the use of the tool) or to a control group. The students were in their senior year of an accelerated second bachelor degree program in a large university in the Northeast. Students randomized to the intervention group conducted a medication history on trained mock patients who had been given a scripted medication list. Mock patients only gave information about their medication history when queried by the student. For example, the mock patient would not offer information about their medication allergies unless specifically asked by the student. Students were allowed 30 minutes to complete the interviews. The accuracy of the medication history obtained by the student was measured by comparing the scripted medication lists with the lists obtained by the student nurse.

Specific Aim 2

A refined tool was implemented on 2 inpatient general medical/surgical units in a 653-bed academic teaching hospital and 2 inpatient units in a 93-bed acute care community hospital for a 1-month period. Nurses were educated using one-on-one training, and each received a laminated copy of the 6-step tool. Posters of the tool and key concepts were prominently displayed on hospital walls during the intervention period and for a 3-month period afterward. The outcome measure was rate of medication errors, which included both an evaluation of the rates of reported medication errors (obtained from the hospital safety reporting system) and rates of medication discrepancies (delays and omissions) as determined by the study researchers.

Rates of reported medication errors for the 3 months before and for 3 months after the 1-month intervention period were compared. Two pharmacists and a nurse with expertise in medication safety independently assessed the likelihood that inaccuracies in the medication history could have contributed to the medication error.

Rates of drug discrepancies before and after the intervention were compared via review of electronic histories, computerized orders, and discharge summaries. Fifty consecutive admissions for the periods immediately before and immediately after the intervention for each of the 4 inpatient units were identified. Each cohort was randomly reduced to a subgroup of 25 using a random number generator with Microsoft Excel to better ensure the final cohort represented the diversity of the hospital providers. For each patient, the electronic medical record was reviewed with a focus on the admitting history and physical report, all inpatient medication orders, and the discharge summary. All medications and allergies noted at each of the 3 points of care (admission, inpatient, and discharge) were catalogued, time stamped, and entered in an Excel spreadsheet. Any change in clinical status noted in the admitting history and physical, which would affect continuation of therapy (e.g., diuretic use in a patient diagnosed with new onset acute renal failure secondary to dehydration) was identified. A clinical pharmacist board certified in pharmacotherapy collected all patient data, and a random selection of records was selected for independent review by a second clinical pharmacist and advanced practice nurse (Table 1).

Specific Aim 3

An investigator-developed survey was administered to a convenience sample of staff nurses 1 month after the intervention period was completed. Questions on the survey related to the use of the tool and approach, time taken to complete the medication history, and any recommendations for changes. The survey tool was developed by the research team who had experience in medication safety and survey development to establish content validity.

Data Analysis

Statistical Methods

All statistical analyses were conducted using Stata 10.1/SE (StataCorp, College Station, Texas). Chi square tests were used

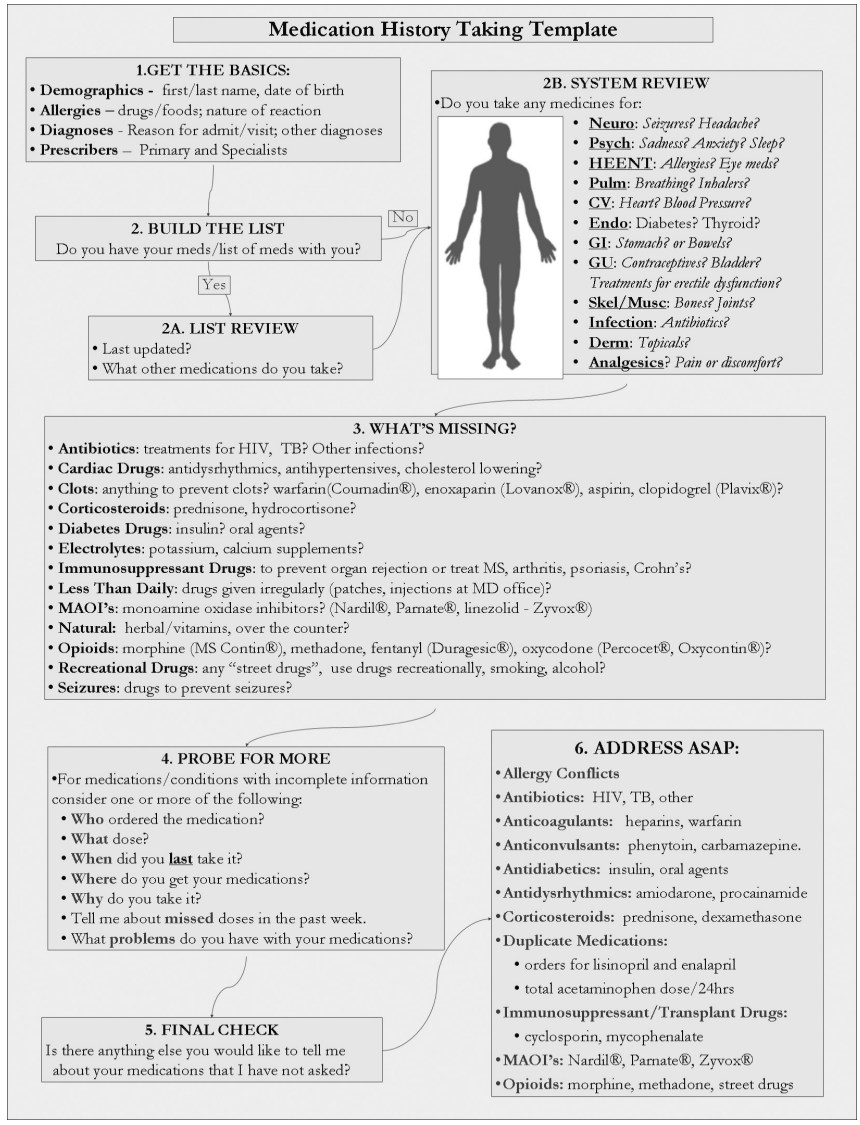

FIGURE 1. Medication history taking tool.

for categorical inferences and for comparisons of proportions, except when cell counts were 3 or lesser, and then, Fisher's exact test was used. For continuous variables, 2-sided *t* tests were used. A *P* value of less than 0.05 was determined to be statistically significant.

RESULTS

Specific Aim 1

A total of 16 senior undergraduate nursing students gave informed consent to participate. Seven students were randomized

TABLE 1. Categories of Discrepancies

Minor Delay (beyond 48 hr)	Time between admission and Provider Order Entry or first dose exceeded 48 hours—likely benign implications (e.g., multivitamin delay)
Important Delay (beyond 48 hr)	Time between admission and Provider Order Entry or first dose exceeded 48 hours—potential clinically important implications (e.g., cardiovascular, antidiabetic, corticosteroid delay)
Minor Omit for Hospital Stay	Drug omitted during hospitalization—likely benign implications (e.g., multivitamin omit)
Important Omit for Hospital Stay	Drug omitted during hospitalization—potential clinically important implications (e.g., cardiovascular, antidiabetic, corticosteroid omit)
Minor Omit in Discharge Summary	Drug omitted in discharge summary—likely benign implications (e.g., multivitamin omit)
Important Omit in Discharge Summary	Drug omitted in discharge summary—potential clinically important implications (e.g., cardiovascular, antidiabetic, corticosteroid omit)

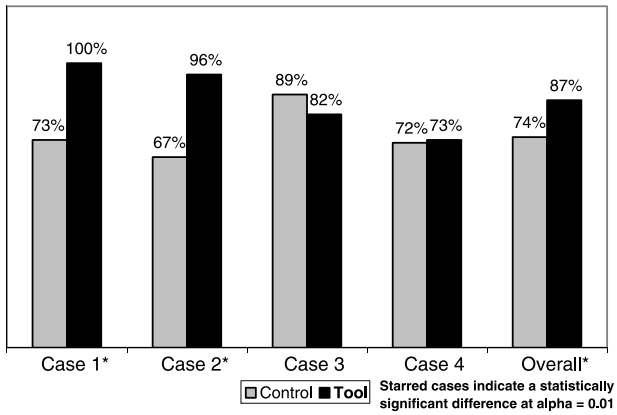

FIGURE 2. Percentages of medications accurately identified by student nurses in the control and experimental groups.

to the treatment group and 9 to the control group. Students using the tool interviewed an average of 1.7 mock patients each, whereas students not using the tool interviewed an average of 1.9 mock patients, and every student interviewed at least 1 mock patient.

Overall reconciliation accuracy was better with students using the tool (87% accuracy) versus not using the tool (74% accuracy) ($P = 0.010$) (Fig. 2). Reconciliation accuracy differed not only by intervention but also by case. For 2 mock patient case scenarios, the tool and education had a dramatic effect on reconciliation accuracy, with the tool resulting in 100% reconciliation versus 73% accuracy in the control group (Fisher exact P value = 0.002) and 96% reconciliation versus 67% accuracy in the second case (Fisher exact P value = 0.013). For the remaining 2 cases, the accuracy was similar between the 2 groups (82% versus 89% for the control; 73% versus 72% for the control). Potassium chloride and nicotine patches were difficult for students to identify with the use of the tool in the intervention group.

Specific Aim 2

Rates of reported medication errors were 35% lower in the 3 months post-intervention compared with pre-intervention in the community hospital but did not reach statistical significance ($P = 0.181$). Similarly, rates of medication errors specifically related to medication history taking were 80% lower post-intervention in the community hospital but did not reach statistical significance ($P = 0.204$). No differences in reported medication error rates were observed in the academic teaching hospital preintervention versus postintervention. There were no reported medication events related to drug allergies during the study.

Review of electronic medical records for the larger teaching hospital identified an inadequate number of electronic history and physical exam records with needed date and time stamps available for analysis. Therefore, this outcome measure was not assessed at the teaching hospital. The electronic medical records were complete and available at the community hospital to allow for an adequate analysis in that setting.

Although no statistically significant differences in demographics or providers were noted between the preintervention and postintervention groups in the community hospital, there was a trend toward more patients from nursing homes in the preintervention group, which may have had higher acuity. There were similar but statistically more medications per patient on average in the preintervention group than the postintervention group (Table 2 and Fig. 3).

The differences in number of drugs per patient between before and after for all 3 groups were significantly different (with postintervention being lower) at alpha = 0.05. Here, each "clear" box plot represents a preintervention total value, whereas the shaded box plot represents its corresponding postintervention total.

Rates of discrepancies before and after intervention are presented in Table 3. The percentage of patients with no discrepancies postintervention was more than double that observed preintervention (42% versus 20% preintervention, $P = 0.017$). There was also a significant reduction of minor medication omissions during the hospital stay (before 1.10 [1.25] versus

TABLE 2. Key Variables in the Community Hospital Pre/Post Group

	Pre-intervention (n = 50)	Post-intervention (n = 50)	*P*
Age	68.1 (18.9)	69.3 (18.4)	0.756
% Male/female	M: 53.8%	M: 46.1%	0.423
	F: 46.2%	F: 53.9%	
Providers*			
Hospitalist	35 (71.4%)	33 (66.0%)	0.623
General medical (nonhospitalist)	8 (16.3%)	8 (16.0%)	
Surgeon	5 (10.2%)	9 (18.0%)	
Obstetric	1 (2.0%)	0 (0%)	
Location			
Home	37 (74%)	45 (90%)	0.083
Nursing home	9 (18%)	4 (8%)	
Group home	1 (2%)	0 (0%)	
Hospital	2 (4%)	0 (0%)	
Rest home	0 (0%)	1 (1%)	
Other	1 (2%)	0 (0%)	

Data presented as mean (standard deviation) or as counts (percentage).

*1 missing value in the preintervention group.

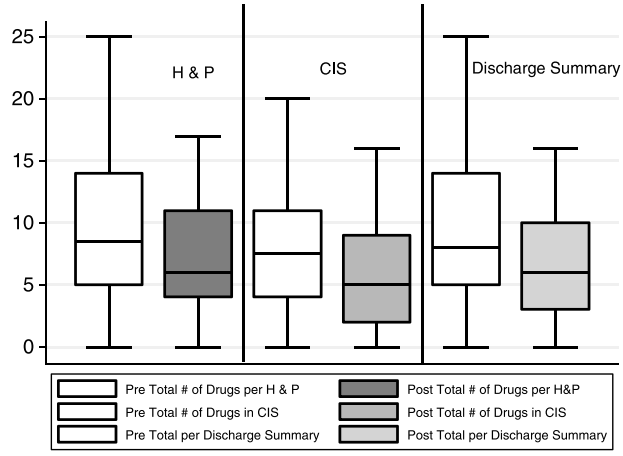

FIGURE 3. Box plot of the number of drugs per patient at the community hospital (H&P-History and Physical, CIS-Clinical Information System).

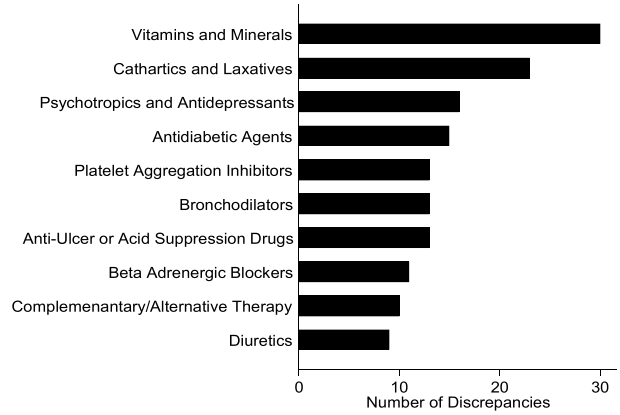

FIGURE 4. Top 10 most frequent drug classes observed in discrepancies: these drugs represent 54.3% of all observed discrepancies.

post 0.60 [1.25], $P = 0.003$) and a trend toward the reduction of important drug omissions in the discharge summary (pre 0.43 [0.71] versus post 0.18 [0.44], $P = 0.053$). There were no significant differences in the number of allergy discrepancies or in length of stay before and after intervention.

Among the more frequently observed drug classes involved in discrepancies were psychotropic/antidepressants, agents for diabetes management, bronchodilators/ respiratory treatments, and antiplatelet medications. Figure 4 shows a histogram of the top ten medication classes observed in discrepancies.

Specific Aim 3

Overall, nurses indicated that the tool and process were useful but more time consuming than their standard process. Most nurses appreciated the structured, systematic approach offered by the tool. A consistent recommendation was to use this approach earlier in the patient stay by the emergency department or by the admitting nurse. A number of new nursing graduates reported that this tool represented what was learned in nursing school, whereas others reported that the tool would have been helpful to have as students when learning the process of taking a medication history.

DISCUSSION

The results of this study suggest that the use of a structured, systematic approach to obtaining a medication history is effective in improving the accuracy and completeness of the admission medication list. In addition, our findings of discrepancies in the medication list obtained on admission are similar to other studies.[7,8,12,23]

A variety of methods have been attempted to improve the process of collecting a comprehensive medication history on admission to the hospital, but little effort has focused on nurses, despite their central role in this process[19] Although the medication list depends heavily on a team approach,[7,9–11,24] It is that nurses be prepared to obtained an initial list and recognize what medications require immediate reconciling.[25] Most studies to date have focused on the role played by the pharmacist or

TABLE 3. Pre Versus Post Percentages and Rates of Discrepancies for the Community Hospital

	Preintervention	Postintervention	
	Mean (SD)	Mean (SD)	*P*
Minor delay (beyond 48 h) rate	0.14 (0.50)	0.14 (0.64)	1.000
Important delay (beyond 48 hrs) rate	0.22 (0.62)	0.20 (0.57)	1.000
Minor omit for hospital stay rate	1.10 (1.25)	0.60 (1.25)	0.048
Important omit for hospital stay rate	0.63 (1.24)	0.58 (1.36)	0.848
Minor omit in discharge summary rate	0.28 (0.83)	0.06 (0.24)	0.075
Important omit in discharge summary rate	0.43 (0.71)	0.18 (0.44)	0.037
Allergy discrepancy rate	0.14 (0.35)	0.10 (0.3)	0.541
Length of stay in days	4.20 (5.09)	4.02 (2.86)	0.822
Preintervention %; (n/N)	**Postintervention %; (n/N)**	***P***	
Percentage of patients with no discrepancies	20%; (10/50)	42%; (21/50)	0.017
Percentage of patients with no minor delays	90%; (45/50)	94%; (47/50)	0.715
Percentage of patients with no important delay	86%; (43/50)	86%; (43/50)	1.000
Percentage of patients with no minor omit for hospital stay	40%; (20/50)	70%; (35/50)	0.003
Percentage of patients with no important omit for hospital stay	67%; (33/49)	76%; (38/50)	0.339
Percentage of patients with no minor omit in discharge summary	84% (42/50)	94%; (47/50)	0.200
Percentage of patients with no important omit in discharge summary	67%; (33/49)	84%; (42/50)	0.053

physician in compiling a comprehensive list, but this approach may not be practical outside of a research setting or large academic medical center.[14,23,26] Our findings are similar to other studies that used pharmacist-obtained medication histories with standardized methodologies.[27,28]

The positive impact of the intervention in the community hospital setting may have been related, in part, to the active day-to-day involvement of the clinical pharmacist who had worked with most of the nurses prior to the implementation of the tool and who offered ongoing support and reinforcement during the implementation period. The pharmacist also facilitated presentation of the tool in a manner which integrated it into existing nursing practice. In addition, nurses in this setting were able to articulate the value of obtaining an accurate medication history. Nursing perception is likely an important factor in the success of any nurse-based medication reconciliation process.[29]

The critical nature of the medication discrepancies reported in our study (e.g., antipsychotics, antidepressants, antidiabetics, antiplatelet medications, and beta-blockers) is concerning, although similar findings have been reported by other researchers.[14,16,30,31] Although the identification of an agent involved in a discrepancy may be related to lack of documentation in the medical record, the methodology of discrepancy identification did include an assessment of clinical status in the history and physical by the clinical pharmacist. It is possible that certain patients consider drugs that they take on a long-term basis (e.g., psychiatric medications or diabetic agents) to be "normal" or so ingrained into their daily routine that they do not report them when asked if they are taking any medications. It is also possible that certain over the counter medications like vitamins, laxatives, or acid suppression agents are viewed so casually by the public as to not be considered "medications" and are underreported in the medical record. These possibilities are underscored by the findings of other researchers who have described "nonindicated" medications reported by patients. These are medications, such as acid suppression agents and antidepressants, noted in the medication history by the patient but not supported with a medical indication. [31] Their findings support the need to conduct a systematic and structured medication history that is iterative with the patient's medical history.

Limitations

Our sample size was small but similar to previous studies, and we were still able to detect statistically significant differences before and after the use of the tool. Nevertheless, in some contexts, we observed differences that were clinically large but not statistically significant because of the sample size. For example, the total number of errors related to medication history taking at the community hospital did decline by 80%, but the difference was not statistically significant.

The lack of electronic admission history and physical reports at the teaching hospital during the study period prevented us from fully assessing the effect of the intervention in this setting. The hard-copy admitting history and physical reports were not time stamped in a manner that would ensure a consistent measure of the outcomes used in this analysis. However, the lack of any change in the spontaneously reported medication errors at the academic teaching hospital and the trend toward reduction at the community hospital suggests that this intervention may not have been as successful at the teaching hospital setting.

Future Research

Future studies may be better able to capture the effects of this tool (or a similar one) on a more diverse group of institutions and better handle the potential effect of bias, given the trend toward increased acuity and numbers of medications observed in the preintervention group at the community hospital. It should be noted though that the potential for bias with slightly more medications per patient and potentially higher acuity in the preintervention group at the community hospital was at least partially controlled by the use of rate data in our statistical analyses.

CONCLUSIONS

A systematic, structured approach to obtaining the medication history by nurses reduced medication errors in this study. Barriers to success using this approach may include perceived limitations in nursing time and adequate facilities to assure a private, uninterrupted discussion with the patient. We encourage future research in this field on a more diverse group of clinical settings to obtain a more definitive approach to collecting an accurate medication history.

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Original Study

Education to Reduce Potentially Harmful Medication Use Among Residents of Assisted Living Facilities: A Randomized Controlled Trial

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Keywords:
Inappropriate drugs
psychotropic drugs
anticholinergic drugs
polypharmacy
assisted living
randomized controlled trial

A B S T R A C T

Objectives: The objectives of this study were (1) to investigate the effect of nurse training on the use of potentially harmful medications; and (2) to explore the effect of nurse training on residents' health-related quality of life (HRQoL), health service utilization, and mortality.
Design: A randomized controlled trial.
Setting and participants: In total, 227 residents in 20 wards of assisted living facilities in Helsinki were recruited. The 20 wards were randomized into those in which (1) staff received two 4-hour training sessions on appropriate medication treatment (intervention group), and (2) staff received no additional training and continued to provide routine care (control group).
Intervention: Two 4-hour interactive training sessions for nursing staff based on constructive learning theory to recognize potentially harmful medications and corresponding adverse drug events.
Measurements: Use of potentially harmful medications, HRQoL assessed using the 15 dimensional instrument of health-related quality of life, health service utilization, and mortality assessed at baseline, and 6 and 12 months.
Results: During the 12-month follow-up, the mean number of potentially harmful medications decreased in the intervention wards [−0.43, 95% confidence interval (CI) −0.71 to −0.15] but remained constant in the control wards (+0.11, 95% CI −0.09 to +0.31) ($P = .004$, adjusted for age, sex, and comorbidities). HRQoL declined more slowly in the intervention wards (−0.038 (95% CI −0.054 to −0.022) than in the control wards (−0.072 (95% CI −0.089 to −0.055) ($P = .005$, adjusted for age, sex, and comorbidities). Residents of the intervention wards had significantly less hospital days (1.4 days/person/year, 95% CI 1.2 −1.6) than in the control wards (2.3 days/person/year; 95% CI 2.1−2.7) (relative risk 0.60, 95% CI 0.49 −0.75, $P < .001$, adjusted for age, sex, and comorbidities).
Conclusions: Activating learning methods directed at nurses in charge of comprehensive care can reduce the use of harmful medications, maintain HRQoL, and reduce hospitalization in residents of assisted living facilities.

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Trial registration: ACTRN12611001078943.
The authors declare no conflicts of interest.

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Multimorbidity and polypharmacy are highly prevalent in institutional settings. Residents are prone to polypharmacy and use of potentially inappropriate medications (PIMs).[1–3] Frailty and age-related changes in pharmacokinetics and pharmacodynamics mean that residents are susceptible to adverse drug events (ADEs).

Medication use is considered inappropriate when the risks outweigh the benefits, particularly when safer alternatives exist. There are a range of implicit and explicit approaches for defining PIMs.[4–8] Internationally, the most widely used explicit criteria are Beers' Criteria.[4,6,9] Between 36% and 50% of older institutionalized residents use Beers' Criteria medications.[1,10–12] Use of PIMs has been associated with ADEs and preventable hospitalizations.[13]

The Omnibus Budget Reconciliation Act of 1987 succeeded in reducing the use of psychotropic medications in older people in the United States.[14] More recently, meta-analyses and safety warnings have alerted clinicians to the increased risk of stroke and mortality associated with antipsychotic use in people with dementia.[15,16] Psychotropic drugs are associated with an increased risk of falls.[17] Notwithstanding these concerns, psychotropic medication use remains highly prevalent in Finland. Up to 80% of residents in institutional care are administered 1 or more psychotropic medications.[18]

There is an increasing body of evidence in relation to ADEs associated with anticholinergic medications. Anticholinergic medications have peripheral and central anticholinergic side-effects including dry mouth, constipation, and cognitive impairment.[19,20] Anticholinergic medications may increase the risk of hospital admissions.[21] Institutionalized older people with dementia and cognitive impairment may be particularly susceptible to anticholinergic ADEs. Notwithstanding differences in lists of medications considered to have anticholinergic properties, scores obtained from several ranked lists of anticholinergic medications predict clinically significant anticholinergic ADEs in older people.[22]

The Swedish Criteria list nonsteroidal anti-inflammatory drugs (NSAIDs) as potentially inappropriate for older people when used for periods of longer than 2 weeks.[8] Although proton-pump inhibitors (PPIs) may be useful for gastroprotection in general older populations, there is evidence that long-term PPI use may be associated with infections, hip fractures, and even higher mortality when prescribed to frail older people in institutional settings.[23]

Several randomized controlled trials (RCTs) have been conducted to reduce PIM use in nursing homes. However, many previous studies have been of low quality and, therefore, have a risk of bias.[24,25] According to a recent systematic review, educational outreach, on-site education, and pharmacist-led medication review may be useful strategies to reduce PIM use in institutional settings.[24] Educational interventions have succeeded in decreasing the use of psychotropic medications in institutionalized older people,[26–30] and in improving the overall quality of medication prescribing.[31,32] However, relatively few studies have explored the effect of these interventions on older peoples' use of health services.[24,25,31] To our knowledge, no previous RCT has demonstrated that reducing harmful medication use improves older peoples' health-related quality of life (HRQoL).

The objectives of this study were (1) to investigate the effect of nurse training on the use of potentially harmful medications; and (2) to explore the effect of nurse training on residents' HRQoL, health service utilization and mortality.

Methods

Design and Context

This was a RCT in which 20 wards in assisted living facilities in Helsinki, Finland, were randomized to intervention and control arms.[33] The intervention was staff training on harmful medication use using the principles of constructive learning theory. Assisted living facilities provide medical and nursing care to people who are unable to live independently in the community. The level of care is similar to that provided in traditional nursing homes or long-term hospital wards, but the environment is designed to be more home-like. Physicians act as visiting consultants to whom nurses can refer challenging management issues. Unless prompted by nurses to do so, physicians may not see an individual resident more than once a year. This means that nurses have a key role in identifying and assisting to resolve medication-related problems.

The study was approved by the Ethics Committee of the Helsinki University Central Hospital. Written informed consent was obtained from each resident and/or their closest proxy. All study procedures were consistent with good clinical practice and the World Medical Association Declaration of Helsinki. The control wards were offered the staff training on harmful medication use at the conclusion of the study.

Participants

Eligible residents of assisted living facilities in Helsinki were invited to participate at the baseline study nurse visit. The study nurses who recruited the residents were not aware which wards had been randomized to the intervention or control groups. The resident inclusion criteria were age 65 years or older; living permanently in an assisted living facility; Finnish speaking; using at least 1 medication; having an estimated life expectancy >6 months; and being able to provide written informed consent (or have a proxy who is able to provide written informed consent in the case of cognitive impairment).

Data Collection

At the baseline study nurse visit, the nurses retrieved participating residents' demographic data, diagnoses, and medication data. These nurses were independent of the study intervention and unaware of the randomization procedures.

Medication data were extracted directly from each resident's medication administration chart and assessed as the point prevalence on the day of assessment. Medication use was categorized as regular if there was a documented regular sequence of administration. If a resident had 1 or more medications that nurses were permitted to administer on a pro re nata ('as-needed') basis this was also recorded. All medications administered to residents were classified using the Anatomical Therapeutic Chemical (ATC) classification system recommended by the World Health Organization.[34]

Cognition was assessed using the Mini-Mental State Examination,[35] nutritional status was assessed using the Mini-Nutritional Assessment,[36] and HRQoL was assessed using the 15 dimensional instrument of health-related quality of life (15D).[37] Repeated assessments were performed a 6 and 12 months using the same procedures described above. Hospitalizations, use of other health and social services and death dates were retrieved from the medical records and central registers from baseline measurements until December 31, 2012.

Harmful Medication Use

Harmful medication use was operationally defined as use of Beers' Criteria medications, anticholinergic medications, use of multiple psychotropic medications, NSAIDs, and PPIs. The study commenced prior to the publication of the 2012 update to the Beers' Criteria and, therefore, the 2003 version was used.[6,9] The Anticholinergic Risk Scale[38] was used in combination with Beers' Criteria anticholinergic

medications[6] and a previously published Swedish list to categorize medications with anticholinergic properties.[8] Psychotropic medications included antipsychotics (ATC-code N05A), antidepressants (ATC-code N06A), anxiolytics (ATC-code N05B), and hypnotics (ATC-code N05C). NSAIDs included both selective and non-selective NSAIDs (ATC-code M01A). Low-dose acetylsalicylic acid ≤250 mg (ATC-code B01AC06) and topical NSAIDs were excluded evaluating harmful medication use.[8,39]

Randomization

We randomized wards instead of participants to avoid contamination of intervention. All 36 assisted living facility wards in Helsinki use the Minimum Data Set/Resident Assessment Instrument Version 2.0 for Home Care.[40] The Minimum Data Set was used to determine the case-mix of each ward. The 36 wards were assessed for possible participation, and 20 wards were paired into 10 dyads. The wards in each dyad shared similar resident characteristics. A computerized random number generator was then used to randomize 1 ward in each dyad to the intervention arm and the other to the control arm. A person independent of assessment procedure telephoned another person not familiar with the wards or residents to receive the randomization number (intervention or control) for each ward.

Intervention

The intervention comprised two 4-hour training sessions for nursing staff based on the principles of constructive learning theory.[41,42] The training sessions were developed to be activating and interactive. The sessions were designed to enable nurses to better recognize harmful medications and corresponding ADEs.

The first 4-hour afternoon session was primarily lecture-based, but participants were encouraged to present and openly discuss medication-related problems experienced by their own residents. The session involved introducing the list of harmful medications and suitable alternatives. This session also involved discussion about medication use for residents with renal impairment and drug-drug interactions. The second 4-hour afternoon session was case study-based. Using the principles of problem-based learning, the nurses participated in facilitated discussions about medication-related problems. To demonstrate the relevance and importance of the topic, nurses were encouraged to present and discuss actual resident cases from their own wards. Throughout the training sessions, the nurses responsible for medication management were invited to reflect on their own procedures and opportunities for improvement. We also invited physicians to participate in the 2 education sessions. Two out of 3 physicians working in the intervention wards attended 1 of the training sessions.

The list of harmful medications was provided to all nurses working in the intervention wards. Following the training, the nurses were asked to identify potential medication-related problems and bring these to the attention of the consulting physician. When this occurred, it was the physician's responsibility to change or continue a specific medication.

Outcome Measurements

The research nurses performed their assessments at 0, 6, and 12 months. The primary outcome measures were the changes in the proportion of persons using any of the following harmful drugs: Beers' Criteria medications,[6] anticholinergic medications,[6,38] >2 psychotropic medications,[8] NSAIDs,[8] or PPIs[23] and the changes in the mean number of these medications. The secondary outcome measures were change in HRQoL,[37] health service utilization and mortality during the 12-month follow-up.

Statistical Analyses

The sample size calculation was based on the change in prevalence of potentially harmful medication use. The required sample size was calculated as follows: if in the control group, 36% use harmful drugs, the minimum group difference with the assessment is 20%, type I error 5%, and power 80%, which results in 106 per group. The justification for the sample size has been presented previously.[33]All residents assessed at baseline and at least 1 of the 2 follow-ups were included when analyzing changes in the use of medications and HRQoL (modified intention-to-treat analyses). All randomized residents were included when analyzing health service utilization and mortality (intention-to-treat analyses). The data were presented as means with standard deviations (SDs), or numbers with percentages; 95% confidence intervals (CI) were computed for the main outcome measures. Statistical comparisons between the groups were performed using t tests, Mann-Whitney U tests, or χ^2 tests when appropriate. Repeated measures were analyzed using generalized estimating equations (GEE) models, with appropriate distribution and link functions, and an unstructured correlation structure, with treatment groups, time and their interaction as fixed factors. GEE models were developed as an extension of general linear models (eg, OLS regression analysis) for analysis of longitudinal and other correlated data. The GEE models took into account the correlation between repeated measurements from the same participant. These models do not require complete data from all participants at all time points. Incidence rates of hospital days and ambulatory services were estimated and compared between the groups using the Poisson regression models with robust standard error [incidence rate ratio (IRR)]. A Cox proportional hazard model was used to test whether ward allocation to intervention or control group was an independent risk factor for mortality. The normality of the variables was tested by using Shapiro-Wilk W tests. All analyses were adjusted for age, gender and comorbidities. The statistical analyses were performed using STATA 13.1, StataCorp LP (College Station, TX).

Results

Of 307 eligible residents, 227 residents or their proxies provided consent to participate (Figure 1). The intervention group included 118 residents and the control group included 109 residents. There was a moderate attrition rate, with 41 residents (18.1%) lost to follow-up at 6 months. The total study attrition at 12 months was 63 residents (27.8%). This included 63 deaths (39 intervention residents, 24 control residents). In addition, data collection was not possible for 3 residents at the 6-month follow-up (1 intervention resident, 2 control residents).

The mean age of the participating residents was 83 years, and 93% were diagnosed with dementia (Table 1). At baseline, the residents in the intervention group had higher number of comorbidities and lower HRQoL than those in the control group. The percentage of males in the intervention group was higher than in the control group. The prevalence of pro re nata ('as-needed') medications was higher in the intervention than in the control group. The mean number of harmful medications was 2.9 (SD 1.8) in the intervention group compared with 2.5 (SD 1.7) in the control group.

Effect of Intervention on the Use of Harmful Medications

The prevalence of harmful medication use decreased significantly in the intervention group (−11.7, 95% CI −20.5 to −2.9; $P = .009$) over the 12-month follow-up period. There was no significant change in

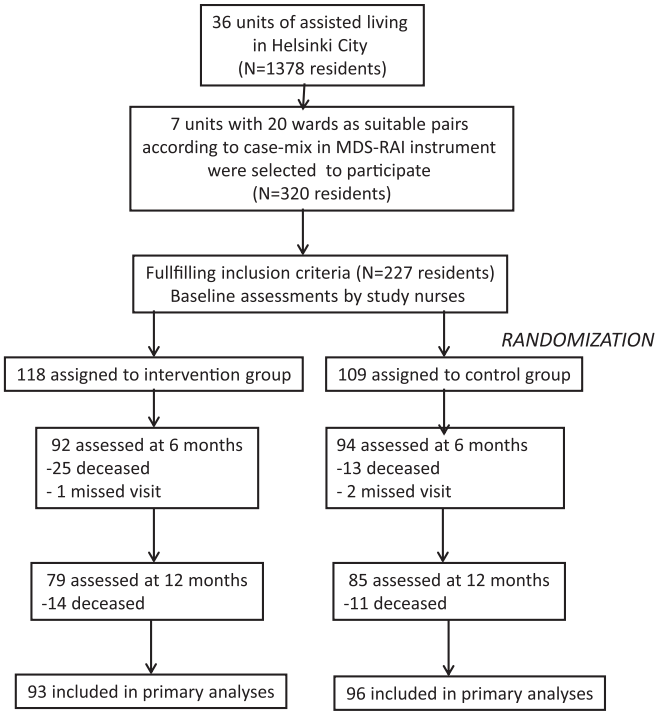

Fig. 1. Flow chart.

the prevalence of harmful medication use in the control group (+3.4%, 95% CI −3.7 to 10.6; $P = .34$). The change in prevalence of harmful medication use was significantly different between the intervention and control groups ($P = .022$, adjusted for age, sex, and comorbidities). The mean number of harmful medications decreased in the intervention group (−0.43, 95% CI −0.15 to −0.71; $P = .0024$) but remained stable in the control group (+0.11, 95% CI −0.09 to +0.31; $P = .27$). The difference in changes of mean number of harmful medications between the intervention and control groups was statistically significant ($P = .0035$, adjusted for age, sex, and comorbidities) (Figure 2, Panel A). Of the harmful drugs, the use of psychotropics decreased significantly in the intervention group compared with controls (Figure 2, Panel B).

Effect of the Intervention on HRQoL and Use of Health Services

HRQoL declined significantly more slowly in the intervention group (−0.038; 95% CI −0.054 to −0.022) compared with the control group (−0.072; 95% CI −0.089 to −0.055) ($P = .005$, adjusted for age, sex, and comorbidities). The dimensions of 15D, which demonstrated significant differences in favor of intervention group, were breathing, sleeping, and speech (Figure 3).

Residents in the intervention group used significantly less hospital days (1.4 /person/year; 95% CI 1.2–1.6) compared with residents in the control group (2.3/person/year; 95% CI 2.1–2.7) (IRR 0.60, 95% CI 0.49–0.75; $P < .001$, adjusted for age, sex, and comorbidities). There was no significant difference in the use of ambulatory services between the groups (intervention 0.7/person/year, 95% CI 0.5–0.8 vs control 0.6/person/year, 95% CI 0.5–0.8; IRR 0.98, 95% CI 0.69–1.39; $P = .92$, adjusted for age, sex, and comorbidities).

At 12 months, 33% of the residents in the intervention group were deceased compared with 22% of participants in the control group. In Cox proportional hazard model when adjusting for age, sex, and comorbidities, the intervention was not associated with the risk of death (HR 1.04; 95% CI 0.79–1.36, $P = .79$ adjusted for age, sex, and comorbidities).

Discussion

This RCT demonstrated that a relatively light educational intervention in assisted living facilities reduced prescribing of potentially harmful medications, maintained HRQoL and reduced hospitalization. To our knowledge, this is the first RCT to demonstrate an educational initiative to reduce potentially harmful medication use was associated with maintenance of residents' quality of life and lower use of hospital services.

An important strength of this study was its pragmatic design. The light intervention should be well suited for wider adoption. The study assessed quality of life and hospitalization, which are 2 clinically important outcomes for older people. There are also potential limitations in this study. First, the study sample comprised predominately frail older people and, therefore, there was a high attrition rate. We used a modified intention-to-treat analyses to investigate changes in the prevalence and mean number of harmful medications. Health service utilization and mortality was analyzed for all residents who commenced the study. Second, we used a cluster randomized design

Table 1
Baseline Characteristics of Participants

	Intervention Group (N = 118)	Control Group (N = 109)	*P* Value*
Females, %	65.3	77.1	.050
Mean age, (SD)	82.9 (7.5)	83.5 (6.9)	.41
MNA,[36] <17, malnourished, %	16.1	22.9	.31
17–23.5, at risk for malnutrition, %	62.7	61.5	
>23.5, well-nourished, %	21.2	15.6	
Mean Charlson's comorbidity index,[51] (SD)	3.2 (2.0)	2.5 (1.8)	<.004
MMSE,[35] mean (SD)	8.8 (8.2)	10.0 (8.2)	.25
15D[37] score mean (SD)*	0.61 (0.12)	0.66 (0.11)	.002
Mean number of regular medications, (SD)	7.5 (2.8)	7.8 (3.1)	.79
Mean number of pro re nata medications, (SD)	3.6 (2.3)	2.9 (2.0)	.007
Proportion using harmful medications†, %	83.1	71.6	.038
Mean number of harmful medications† (SD)	2.9 (1.8)	2.5 (1.7)	.28
Proportion using Beers' Criteria medications, %	24.6	18.3	.25
Proportion using anticholinergic medications, %	76.3	66.1	.089
Proportion using >2 psychotropic medications	33.9	34.9	.30
Proportion using PPIs, %	42.4	36.7	.38
Proportion using NSAIDs, %	3.3	5.5	.42

15D, 15 dimensional instrument of health-related quality of life; MNA, Mini-Nutritional Assessment; MMSE, Mini-Mental State Examination; NSAID, nonsteroidal anti-inflammatory drug; PPI, proton-pump inhibitor; SD, standard deviation.

*Differences between the groups were tested with χ^2 test or Fischer exact test in categorical variables and with *t* test and Mann-Whitney test in continuous variables.

†Harmful medications were any of the following: Beers Criteria medications, anticholinergic medications, use of multiple psychotropic medications, NSAIDs, and PPIs.

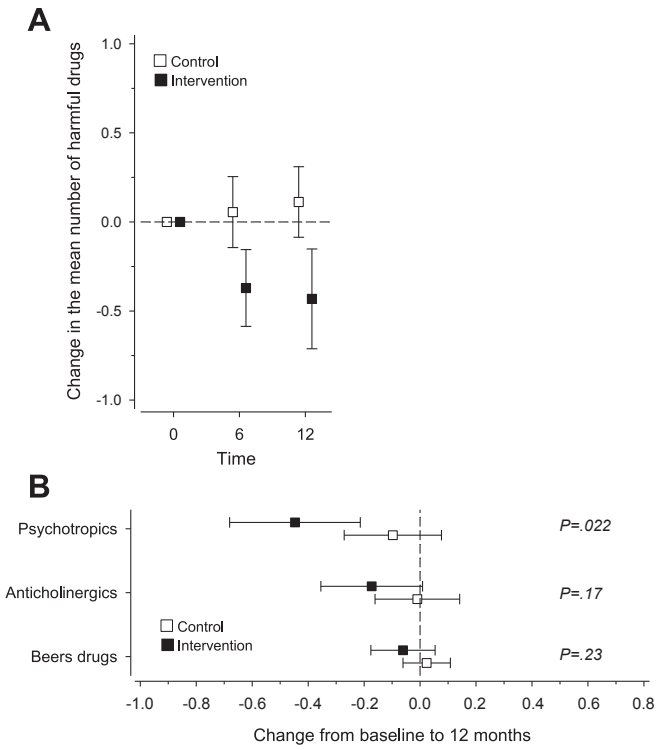

Fig. 2. (A) Changes in the mean number of harmful medications (Beers' Criteria medications,[6] anticholinergic medications,[6,38] >2 psychotropic medications,[8] NSAIDs,[8] or PPIs[23]) during 1-year follow-up relative to baseline (adjusted for age, sex, and Charlson comorbidity index). (B) Changes in the mean number of Beers' Criteria medications,[6] anticholinergic medications,[6,38] and psychotropic medications relative to baseline (adjusted for age, sex, and Charlson comorbidity index). NSAID, nonsteroidal anti-inflammatory drug; PPI, proton-pump inhibitor.

that involved randomizing wards rather than individual residents. This was necessary to avoid potential contamination of the intervention that may have arisen if nurses had provided care to both residents in the intervention and control arms. However, the cluster randomization process was likely responsible for the baseline differences between intervention and control groups for several key parameters. We took this into account by adjusting our analyses for age, sex, and comorbidities.

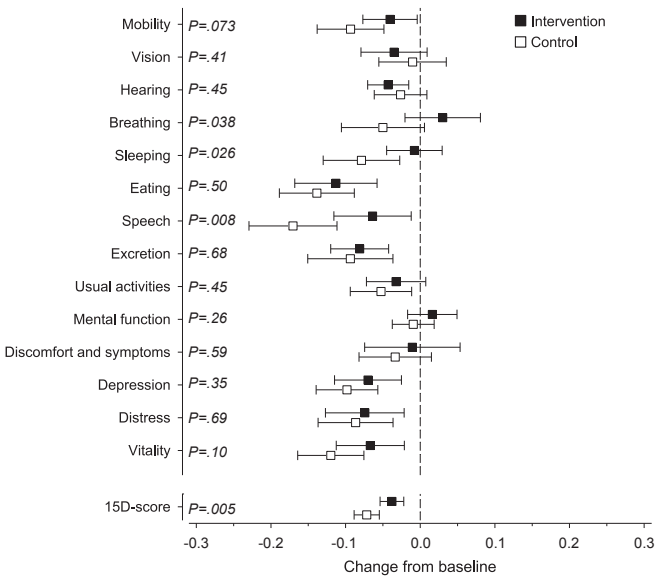

Fig. 3. Changes in 15 dimensional[37] health-related quality of life scores and their dimensions relative to baseline during 12-month follow-up.

The list of medications deemed potentially harmful was based on previous research into ADEs in institutionalized older people.[6,8,13,15–17,19–23] Evidence in relation to risks and benefits of medication treatment for older people in institutional care has expanded in recent years.[43,44] Several validated tools have been developed to identify potentially harmful medications.[6,7,43] However, the applicability of many of these tools is limited by their complexity.[43] In keeping with our desire to investigate a light intervention, we compiled a simple list of harmful medications that have been predictive of poor prognosis.[13,15–17,21–23] These medications are highly prevalent in institutional settings,[10,18,23,45,46] and were easy for the nurses to recognize following the training. The updated version of Beers' Criteria was published after this trial started.[9] However, our list of harmful medications was similar to the list of medications included in the 2012 update to Beers' Criteria. In addition to the previous Beers' Criteria, antipsychotics, benzodiazepines, a large number of anticholinergics, and NSAIDs are now included in the updated Beers' Criteria.[9] Use of these updated criteria would not have changed our results significantly because in our data only 2 residents were using additional drugs (one on spironolactone >25 mg/day and one on sotalol) from the updated Beers' Criteria.[9]

To our knowledge, this is the first large scale trial to demonstrate that educational intervention for reducing harmful medications is associated with positive impacts on residents' QOL and use of health services in institutionalized older people.[25] Several previous trials have demonstrated that educational interventions targeted to nurses and physicians have reduced the use of psychotropic medications.[26–28,30,31] One previous study also involved problem-based learning for nurses.[31] It was successful in reducing psychotropic medications but not in reducing ADEs, hospitalizations, or mortality.[31] To our knowledge, no previous study has been able to demonstrate these effects on health outcomes.[27–31] It has been argued that educational outreach and on-site education may reduce inappropriate medication use.[24] Our study suggests that modern activating learning methods and constructive learning theory may have been important factors for changing practice.[41,42] Education using lectures alone is unlikely to change procedures in health care.[47] Self-directed learning theories include the participation of the learner in defining the problem, applying what has been learned in clinical practice, and subsequent reflection.[48] The nurses were invited to actively reflect on and openly discuss their own medication management practices. Our decision to rely on nurse training reflected their central role in providing comprehensive care for residents of assisted living facilities in Finland. Only those residents who nurses considered to be taking harmful medications or experiencing signs and symptoms suggestive of an ADE are referred for a consultation with a physician.

Another possible factor in the success of the intervention was the high baseline prevalence of harmful medication use. This meant that there was no floor effect in terms of reducing the number of harmful medications. The baseline prevalence of harmful medication use was higher than we had expected. In total, 22% of residents in our study used a Beers' Criteria medication, which was lower than the 36%–50% prevalence reported in previous studies.[1,10–12] However, 85% of residents were administered at least 1 psychotropic medication and 34% of residents were administered 2 or more psychotropic medications. This prevalence is higher than the 49%–80% prevalence of psychotropic medication use reported in previous studies.[18] Overall, 71% of residents were administered 1 or more medications with anticholinergic properties. This was comparable to the prevalence reported in previous studies.[45,46] The

prevalence of PPI use was similar to that reported in previous studies.[49]

There was a decline in HRQoL in both the intervention and control groups, although the decline was significantly lower in the intervention group (−0.038 in the invention group vs −0.072 in the control group). A difference of 0.02–0.03 in 15D scores is considered a clinically significant change as a result of health care interventions.[37] The difference in number of hospital days in favor of the intervention group was surprisingly large. Further research is needed to explore the causes of these hospital admissions. However, medication-related problems are a leading cause of preventable hospital admissions in older people.[50]

Conclusions

It is possible to reduce the number of harmful medications in institutionalized settings by educating nurses to identify harmful medications and ADEs. Modern activating learning methods directed at nurses in charge of residents' comprehensive care can maintain HRQoL and reduce hospitalization. The education initiative did not have a detectable impact on mortality.

Acknowledgments

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SPECIAL ARTICLE

Effect of Bar-Code Technology on the Safety of Medication Administration

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ABSTRACT

BACKGROUND

Serious medication errors are common in hospitals and often occur during order transcription or administration of medication. To help prevent such errors, technology has been developed to verify medications by incorporating bar-code verification technology within an electronic medication-administration system (bar-code eMAR).

METHODS

We conducted a before-and-after, quasi-experimental study in an academic medical center that was implementing the bar-code eMAR. We assessed rates of errors in order transcription and medication administration on units before and after implementation of the bar-code eMAR. Errors that involved early or late administration of medications were classified as timing errors and all others as nontiming errors. Two clinicians reviewed the errors to determine their potential to harm patients and classified those that could be harmful as potential adverse drug events.

RESULTS

We observed 14,041 medication administrations and reviewed 3082 order transcriptions. Observers noted 776 nontiming errors in medication administration on units that did not use the bar-code eMAR (an 11.5% error rate) versus 495 such errors on units that did use it (a 6.8% error rate) — a 41.4% relative reduction in errors ($P<0.001$). The rate of potential adverse drug events (other than those associated with timing errors) fell from 3.1% without the use of the bar-code eMAR to 1.6% with its use, representing a 50.8% relative reduction ($P<0.001$). The rate of timing errors in medication administration fell by 27.3% ($P<0.001$), but the rate of potential adverse drug events associated with timing errors did not change significantly. Transcription errors occurred at a rate of 6.1% on units that did not use the bar-code eMAR but were completely eliminated on units that did use it.

CONCLUSIONS

Use of the bar-code eMAR substantially reduced the rate of errors in order transcription and in medication administration as well as potential adverse drug events, although it did not eliminate such errors. Our data show that the bar-code eMAR is an important intervention to improve medication safety. (ClinicalTrials.gov number, NCT00243373.)

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Medication errors in hospitals are common[1,2] and often lead to patient harm. One study identified 6.5 adverse events related to medication use per 100 inpatient admissions; more than one fourth of these events were due to errors and were therefore preventable.[2] Among serious medication errors, about one third occur at the ordering stage of the medication process, another third occur during medication administration, and the remaining third occur in about equal numbers during the transcription and dispensing stages.[3]

Health care information technology has been touted as a promising strategy for preventing medication errors.[4-6] For example, computerized physician-order entry has been shown to reduce the incidence of serious medication errors by 55%.[7] Bar-code verification technology, ubiquitous in industries outside the field of health care, is another example. Previous studies have shown that this technology can prevent errors in dispensing drugs from the pharmacy[8] and in counting sponges in the operative setting.[9] At the bedside, the use of bar-code technology to verify a patient's identity and the medication to be administered is a promising strategy for preventing medication errors, and its use has been increasing, most notably in Veterans Affairs hospitals.[10] Bar-code medication verification at the bedside is usually implemented in conjunction with an electronic medication-administration system (eMAR), allowing nurses to automatically document the administration of drugs by means of bar-code scanning. Because the eMAR imports medication orders electronically from either the physician's order entry or the pharmacy system, its implementation may reduce transcription errors. Given its potential to improve medication safety, bar-code eMAR technology is being considered as a criterion for achieving "meaningful use" of health information technology and for obtaining financial incentives under the American Recovery and Reinvestment Act of 2009 in 2013.[11]

Evidence of the effectiveness of the bar-code eMAR technology, however, has been limited and mixed.[12-17] Moreover, several studies have highlighted certain unintended consequences of its implementation, with some users either bypassing this technology or relying on it too much, thus increasing the risk of new errors.[18-22] Given the uncertainties about the bar-code eMAR technology, we evaluated its implementation in a large tertiary care medical center to assess its effects on administration and transcription errors, as well as on associated potential adverse drug events.

Methods

Overview of Bar-Code eMAR Technology

Bar-code eMAR technology incorporates several technologies into the workflow of the nursing staff to ensure that the correct medication is administered at the correct dose at the correct time to the correct patient. Traditionally, medication orders placed by physicians are manually transcribed to the paper medication-administration record, which in turn is used by nurses to determine what medications to administer and when. With the bar-code eMAR, medication orders appear on the patient's electronic record once the pharmacist has approved them. Furthermore, if a patient's medication is overdue, the nurse will be alerted through an electronic patient worklist.

In the traditional paper-driven process of administering drugs, the nurse manually verifies the dose and the patient's identity before the medication is given. Bar-code eMAR provides an additional layer of safety by requiring nurses to scan the bar codes on the patient's wristband and on the medication before it is administered. If the dose being scanned corresponds to a pharmacist-approved medication order and the patient is due for this dose, administration is automatically documented. However, if the dose does not correspond to a valid order, the application issues a warning.

For a more detailed description of how nurses use this technology and for a list of the features it supported during the study period, see Appendix A and Appendix B, respectively, in the Supplementary Appendix, available with the full text of this article at NEJM.org.

Study Design

Over a 9-month period in 2005, we determined the rate of errors related to transcribing orders and administering medications in 35 adult medical, surgical, and intensive care units in a 735-bed tertiary academic medical center. In the study year, physicians (or physician extenders) wrote approximately 1.7 million medication orders and nurses administered approximately 5.9 million doses of

medications. Using a prospective, before-and-after, quasi-experimental study design, we compared error rates in units that were using the bar-code eMAR technology with the rates in units that had not implemented it.

ROLLOUT PLAN

After a brief pilot period, the hospital began implementing the bar-code eMAR technology at the bedside in April 2005. Between 2 and 4 patient-care units began using this technology every 2 weeks until, by July 2005, all 35 units had completely implemented it. Before each period of rollout, nurses received 4 hours of hands-on classroom training in medication scanning and use of the eMAR application. During the 2-week rollout period, the hospital provided specially trained nurses during all nursing shifts on the participating units to support the nurses who were learning to use the new technology. The hospital's information systems department also provided continuous onsite support during the rollout period.

The clinical decision was made to delay the rollout of the bar-code eMAR technology on oncology units because of the complex protocols, dosing regimens, and specialized workflow for administering medications to these patients. Therefore, these units were not included in the study.

STUDY OUTCOMES

We defined two main outcomes for administration errors: errors in timing (involving administrations that were early or late by more than 1 hour) and errors unrelated to timing. These two outcomes were defined separately because there was no broad agreement in the literature regarding what constitutes an early or a late medication administration. The unit of analysis for administration errors was the presence or absence of an error in the dose of medication administered during the observation period; the unit of analysis for transcription errors was the presence or absence of an error in the transcribed medication order.

DATA COLLECTION AND ADJUDICATION

Trained research nurses directly observed order transcription and medication administration in each study unit 2 to 4 weeks before the bar-code eMAR rollout and then 4 to 8 weeks afterward. Because of the staggered nature of the rollout, observations were made simultaneously in units with and those without the bar-code eMAR during approximately half the observation period, which lasted from February through October 2005.

We used a direct-observation method to measure error rates.[23] Research nurses shadowed staff nurses on the observation units for 4 hours and, without knowing the physician's medication orders, recorded details about the medications being administered to patients. On the rare occasion when a research nurse believed that a medication was being administered erroneously by a staff nurse, the research nurse intercepted the administration and recorded that attempt as an administration error. After completing the observation session, the research nurses, assisted by research pharmacists, reviewed the physicians' orders and either the paper record of medication administration (on units without the bar-code eMAR) or the eMAR (on units with the bar-code eMAR). Using these documents, they determined whether there were any transcription errors (i.e., errors in the transcription of physicians' orders for medications administered during the observation period) or any administration errors (i.e., errors in administering medications, based on what the nurses had directly observed).

Each administration error and transcription error was classified by a member of the study staff according to the type of error (Appendix C in the Supplementary Appendix). Each error was further adjudicated independently by two members of a multidisciplinary panel consisting of physicians, nurses, and pharmacists to confirm the presence of an error and the potential for that error to lead to patient harm (a subgroup known as potential adverse drug events). Harm was further classified as clinically significant, serious, or life-threatening.[24] Any disagreements between the two panel members concerning the presence of an error or the severity of potential harm were resolved by consensus.

STATISTICAL ANALYSIS

Rates of administration errors related to timing, those unrelated to timing, and transcription errors were compared between units with the bar-code eMAR and those without it. Unadjusted error rates were compared with the use of the Rao–Scott chi-square test,[25] accounting for clustering by nurse (i.e., multiple observations of medications administered by the same nurse). To adjust for possible confounders, such as unit type, we built clustered logistic-regression models[26] with

presence of error as the dependent variable. Statistical analyses were performed with the use of SAS software, version 9.1 (SAS Institute).

RESULTS

We observed 6723 medication administrations on patient units that did not have bar-code eMAR and 7318 medication administrations on patient units that did. Most of the observations occurred during a weekday nursing shift (7 a.m. to 3 p.m.). Table 1 lists the types of medications for which administration was observed and the characteristics of the patients who received them.

NONTIMING ERRORS IN MEDICATION ADMINISTRATION

On units without the bar-code eMAR, we observed 776 nontiming medication-administration errors (an 11.5% error rate), whereas on units with the bar-code eMAR, we observed 495 nontiming medication-administration errors (a 6.8% error rate), representing a 41.4% relative reduction in the rate of such errors (P<0.001) (Table 2). The rate of potential adverse drug events due to nontiming administration errors fell from 3.1% to 1.6%, representing a 50.8% relative reduction (P<0.001). Significant reductions were seen in potential adverse drug events with a severity rating of significant (a 48.5% reduction) or serious (a 54.1% reduction); the rate of potential adverse drug events that were life-threatening did not change significantly.

We observed significant relative reductions in many subtypes of nontiming medication-administration errors, including those that the bar-code eMAR was expected to reduce. For example, wrong-medication errors were reduced by 57.4%, wrong-dose errors by 41.9%, and administration-documentation errors by 80.3%. There were significant reductions in potential adverse drug events associated with administration-documentation errors (80.3% reduction) and wrong-dose errors (33.0% reduction).

Significant reductions were seen in rates of nontiming administration errors and of associated potential adverse drug events on the surgical units (44.9% and 56.1%, respectively; P<0.001 for both) and on the intensive care units (42.5% [P=0.001] and 69.3% [P<0.001]). On the medical units, which had the lowest error rate at baseline among the three types of units, the rate of medical errors was reduced by 25.1% (P=0.03), but the rate of potential adverse drug events was reduced by only 11.1% (P=0.59).

TIMING ERRORS IN MEDICATION ADMINISTRATION

The overall incidence of medication doses directly observed to be administered either early or late decreased from 16.7% without the bar-code eMAR to 12.2% with its use (a reduction of 27.3%; P=0.001) (Table 3). The majority of these errors were due to administrations that were late by 1 to 2 hours, which fell by 23.9% with use of the bar-code eMAR. The incidence of potential adverse drug events due to late or early administration did not differ significantly between the units with and those without the bar-code eMAR technology.

TRANSCRIPTION ERRORS

We reviewed 1799 orders on units without the bar-code eMAR and observed 110 transcription errors, of which 53 were potential adverse drug events, corresponding to 6.1 transcription errors and 2.9 potential adverse drug events per 100 medication orders transcribed (Table 4). In the 1283 medication orders reviewed on units with the bar-code eMAR, no transcription errors occurred (P<0.001 for transcription errors and for potential adverse drug events due to such errors, by Fisher's exact test).

Errors intercepted by the bar-code eMAR during the 2 years after the implementation period are shown in Appendix D in the Supplementary Appendix.

DISCUSSION

The implementation of bar-code medication-verification technology embedded in an eMAR was associated with a 41% reduction in nontiming administration errors and a 51% reduction in potential adverse drug events from these errors. Errors in the timing of medication administration fell by 27%, although we did not see any significant change in associated potential adverse drug events. Transcription errors and associated potential adverse drug events were essentially eliminated. Because the study hospital administers approximately 5.9 million doses of medications per year, use of the bar-code eMAR is expected to prevent approximately 95,000 potential adverse drug events at the point of medication administration every year in this hospital. The technology is also ex-

Table 1. Characteristics of 14,041 Observed Medication Administrations and 1726 Patients on Hospital Units with and Those without the Bar-Code eMAR.*

Characteristic	Units without Bar-Code eMAR	Units with Bar-Code eMAR	P Value
Medication administrations			
Doses observed — no./total no. (%)	6723/14,041 (47.9)	7318/14,041 (52.1)	
Medical unit	2008/6723 (29.9)	2232/7318 (30.5)	<0.001†
Surgical unit	3528/6723 (52.5)	3856/7318 (52.7)	
Intensive care unit	1187/6723 (17.7)	1230/7318 (16.8)	
Classification of agent — no./total no. of doses (%)	6723/14,041 (47.9)	7318/14,041 (52.1)	<0.001†
Antibiotic	571/6723 (8.5)	668/7318 (9.1)	
CNS, pain, psychiatric	954/6723 (14.2)	870/7318 (11.9)	
Cardiovascular	1090/6723 (16.2)	1180/7318 (16.1)	
Endocrine, cholesterol-lowering	488/6723 (7.3)	669/7318 (9.1)	
Gastrointestinal, nutritional	2062/6723 (30.7)	2128/7318 (29.1)	
Hematologic	668/6723 (9.9)	810/7318 (11.1)	
Pulmonary	149/6723 (2.2)	246/7318 (3.4)	
Renal, electrolytes	435/6723 (6.5)	415/7318 (5.7)	
Other	306/6723 (4.6)	332/7318 (4.5)	
Patients			
Overall — no./total no. (%)	787/1726 (45.6)	939/1726 (54.4)	<0.001†
Medical unit	204/787 (25.9)	261/939 (27.8)	
Surgical unit	469/787 (59.6)	537/939 (57.2)	
Intensive care unit	114/787 (14.5)	141/939 (15.0)	
Women — %			0.41‡
Medical unit	47	52	
Surgical unit	46	47	
Intensive care unit	47	49	
Age — yr			0.93§
Medical unit	64.3±17.1	64.6±16.5	
Surgical unit	58.5±17.0	58.4±17.8	
Intensive care unit	62.4±16.7	61.3±15.3	

* Plus–minus values are means ±SD. CNS denotes central nervous system, and GI gastrointestinal.
† The P value was calculated with the use of the chi-square test.
‡ The P value was calculated with the use of the Cochran–Mantel–Haenszel test.
§ The P value was calculated with the use of the stratified Wilcoxon test.

pected to reduce the number of late or early administrations by about 270,000 per year. Given that the electronic order-entry system at the study hospital processed about 1.69 million medication orders during the study year, the eMAR system is also expected to prevent approximately 50,000 potential adverse drug events related to transcription errors.

Although pharmacists and nurses often intercept errors during the medication-ordering stage, errors made during the administration stage and, to a lesser extent, during the medication-transcription stage often go undetected.[3] This finding highlights the need for highly reliable strategies such as bar-code technology to act as an additional safety net in medication administration. The close integration of the order-entry, pharmacy, and medication-administration systems ensures that nurses administer medications only after pharmacists have clinically reviewed the medication orders (except for medications used in emer-

Table 2. Nontiming Medication-Administration Errors and Potential Adverse Drug Events on Units without and Those with the Bar-Code eMAR.*

Nontiming Administration Errors	Medication Errors				Potential Adverse Drug Events			
	Units without Bar-Code eMAR (N=6723 doses)	Units with Bar-Code eMAR (N=7318 doses)	Relative Change in Error Rate	P Value	Units without Bar-Code eMAR (N=6723 doses)	Units with Bar-Code eMAR (N=7318 doses)	Relative Change in Error Rate	P Value
	no. of errors (% of doses)		*% (95% CI)*		*no. of errors (% of doses)*		*% (95% CI)*	
Total errors	776 (11.5)	495 (6.8)	−41.4 (−34.2 to −47.6)	<0.001	213 (3.1)	114 (1.6)	−50.8 (−39.1 to −61.7)	<0.001
Error type								
Oral vs. nasogastric-tube administration	298 (4.4)	260 (3.6)	−19.9 (−6.6 to −33.3)	0.003	0	0	—	—
Error in administration documentation	192 (2.9)	41 (0.6)	−80.3 (−73.7 to −87.0)	<0.001	86 (1.3)	18 (0.2)	−80.3 (−70.7 to −90.5)	<0.001
Dose error	136 (2.0)	84 (1.1)	−41.9 (−27.9 to −58.7)	<0.001	63 (0.9)	46 (0.6)	−33.0 (−10.5 to −59.6)	0.005
Wrong medication	64 (1.0)	29 (0.4)	−57.4 (−39.2 to −76.3)	<0.001	9 (0.1)	10 (0.1)	2.1 (−89.8 to 93.7)	0.97
Error in directions, monitoring, or both	37 (0.6)	46 (0.6)	18.9 (−33.9 to 68.4)	0.51	28 (0.4)	32 (0.4)	10.0 (−47.0 to 64.4)	0.76
Administration without order	19 (0.3)	8 (0.1)	−60.7 (−29.4 to −93.3)	<0.001	12 (0.2)	2 (0.03)	−83.3 (−70.7 to −90.5)	<0.001
Errors in routes of administration other than oral or nasogastric tube	17 (0.3)	6 (0.1)	−68.0 (−37.4 to −97.7)	<0.001	7 (0.1)	2 (0.03)	−70.0 (−32.6 to −99.9)	<0.001
Other errors	16 (0.2)	21 (0.3)	20.5 (−57.9 to 98.7)	0.61	8 (0.1)	4 (0.05)	−54.0 (−99.9 to 0.9)	0.05
Location of patient								
Medical unit	107 (1.6)	85 (1.2)	−25.1 (−3.5 to −46.5)	0.03	44 (0.7)	41 (0.6)	−11.1 (−49.0 to 28.1)	0.59
Surgical unit	345 (5.1)	207 (2.8)	−44.9 (−35.8 to −54.7)	<0.001	110 (1.6)	53 (0.7)	−56.1 (−41.9 to −70.5)	<0.001
Intensive care unit	324 (4.8)	203 (2.8)	−42.5 (−32.6 to −52.7)	0.001	59 (0.9)	20 (0.3)	−69.3 (−53.9 to −84.9)	<0.001
Severity of potential adverse drug events								
Clinically significant	—	—	—		123 (1.8)	69 (0.9)	−48.5 (−33.9 to −64.0)	<0.001
Serious	—	—	—		88 (1.3)	44 (0.6)	−54.1 (−36.8 to −70.4)	<0.001
Life-threatening	—	—	—		2 (0.03)	1 (0.01)	−53.9 (−99.9 to 56.4)	0.34

* P values have been adjusted for unit type and for multiple observations by the same nurses. For definitions and examples of error types, see Appendix C in the Supplementary Appendix, available with the full text of this article at NEJM.org.

Table 3. Timing Administration Errors and Potential Adverse Drug Events on Units without and Those with the Bar-Code eMAR.*

Administration Errors Related to Timing	Medication Errors				Potential Adverse Drug Events			
	Units without Bar-Code eMAR (N=6723 doses)	Units with Bar-Code eMAR (N=7318 doses)	Relative Change in Error Rate	P Value	Units without Bar-Code eMAR (N=6723 doses)	Units with Bar Bar-Code eMAR (N=7318 doses)	Relative Change in Error Rate	P Value
	no. of errors (% of doses)		*% (95% CI)*		*no. of errors (% of doses)*		*% (95% CI)*	
Total errors	1126 (16.7)	891 (12.2)	–27.3 (–21.0 to –33.8)	0.001	34 (0.5)	30 (0.4)	–18.9 (–60.4 to 25.5)	0.44
Early administration	144 (2.1)	73 (1.0)	–53.3 (–40.4 to –66.6)	<0.001	4 (0.06)	3 (0.04)	–33.3 (–99.9 to 72.1)	0.56
1 to 2 hr early	108 (1.6)	63 (0.9)	–46.6 (–29.8 to –63.1)	<0.001	—	—	—	—
>2 to 4 hr early	27 (0.4)	5 (0.1)	–82.5 (–66.8 to –99.2)	0.001	3 (0.04)	1 (0.01)	–75.0 (–99.9 to 0.02)	0.05
>4 hr early	9 (0.1)	5 (0.1)	–46.1 (–99.9 to 6.8)	0.09	1 (0.01)	2 (0.03)	100 (–99.0 to 99.9)	0.71
Late administration	982 (14.6)	818 (11.2)	–23.6 (–16.5 to –30.7)	<0.001	30 (0.4)	27 (0.4)	–17.8 (–60.4 to 25.5)	0.43
1 to 2 hr late	783 (11.6)	649 (8.9)	–23.9 (–16.0 to –31.9)	<0.001	—	1 (0.01)	—	—
>2 to 4 hr late	175 (2.6)	128 (1.7)	–33.0 (–17.6 to –48.2)	<0.001	25 (0.4)	17 (0.2)	–37.8 (–76.0 to 0.84)	0.06
>4 hr late	24 (0.4)	41 (0.6)	55.6 (–22.2 to 99.9)	0.16	5 (0.07)	9 (0.1)	71.4 (–99.0 to 99.9)	0.48

* P values have been adjusted for unit type and for multiple observations by the same nurses. CI denotes confidence interval. For definitions and examples of error types, see Appendix C in the Supplementary Appendix, available with the full text of this article at NEJM.org.

gencies), allowing patients to benefit more fully from pharmacists' clinical knowledge. Preventing transcription errors is also important, especially since each erroneous transcription can lead to repeated erroneous administrations. Given the high number of doses administered and orders transcribed in any acute care hospital, implementation of the bar-code eMAR could substantially improve medication safety.

The effect of the bar-code eMAR in our study was similar to the effect of the early implementation of computerized physician-order entry, which reduced serious medication errors at the ordering stage by 55%.[7] Decision support embedded within computerized physician-order entry systems is more likely to prevent errors that result from bad judgment, insufficient knowledge, or incomplete clinical information when choosing a therapeutic plan; in contrast, the bar-code eMAR system is more likely to prevent errors associated with memory lapses or mental slips in executing a therapeutic plan. As such, the two technologies would probably play complementary roles in improving medication safety in acute care hospitals. Further research is needed to determine the relative values of computerized physician-order entry and the bar-code eMAR system when resources do not permit a particular hospital to implement the two technologies simultaneously. The proportion of serious medication errors committed and the magnitude of the reduction in serious errors by health information technology at the four stages of the inpatient medication process may inform that line of research (Fig. 1).

Our study suggests that the prevention of many of the potential adverse drug events could be attributed to the reduction in documentation errors. This finding may lead some to conclude that the eMAR component of the bar-code eMAR may have greater effect than the medication-verification component. However, our experience in studying the workflow of the medication-administration process suggests that the medication-verification component greatly facilitates the documentation process for nurses and may be an important factor for its acceptance.[27] Previous research in human-factors engineering also suggests that new errors may be introduced if busy clinicians are asked to select medications from a list of multiple medications due to be administered and then to document the administration times using a keyboard and a mouse.[28,29] In addition, by the time

Table 4. Transcription Errors, Medication Errors, and Potential Adverse Drug Events on Units without and Those with the Bar-Code eMAR for 3082 Orders Reviewed.*

Transcription Errors	Medication Errors		Potential Adverse Events	
	Units without Bar-Code eMAR (N=1799 orders)	Units with Bar-Code eMAR (N=1283 orders)	Units without Bar-Code eMAR (N=1799 orders)	Units with Bar-Code eMAR (N=1283 orders)
	no. of errors (% of orders)			
Total errors	110 (6.1)	0	53 (2.9)	0
Type of error				
Error in directions	68 (3.8)	0	31 (1.7)	0
Error in frequency of administration	10 (0.6)	0	3 (0.2)	0
Order not transcribed	5 (0.3)	0	5 (0.3)	0
Error in route of administration	4 (0.2)	0	1 (0.1)	0
Unacceptable abbreviation	4 (0.2)	0	4 (0.2)	0
Dose error	3 (0.2)	0	0	0
Illegible transcription of order	2 (0.1)	0	2 (0.1)	0
Substitution error	2 (0.1)	0	1 (0.1)	0
Wrong time of administration	1 (0.1)	0	0	0
Duplicate transcription from single order	1 (0.1)	0	0	0
Medication not discontinued as ordered	1 (0.1)	0	0	0
Other errors	9 (0.5)	0	6 (0.3)	0
Severity of potential adverse events				
Significant	—	—	28 (1.6)	0
Serious	—	—	24 (1.3)	0
Life-threatening	—	—	1 (0.1)	0

* Because results were zero for all observations in which the bar-code eMAR was used, we could not build multivariable models to compute adjusted P values. For definitions and examples of error types, see Appendix C in the Supplementary Appendix, available with the full text of this article at NEJM.org.

we conducted the current study, our study hospital had already implemented bar-code verification in the pharmacy, resulting in significantly fewer wrong medications found in the areas where medications are stored.[8] Our results likely represent a lower boundary with respect to the effect of the medication-verification step. Further study may be necessary to address the relative importance of the two main components of the bar-code eMAR.

Although the rate of medication-administration errors fell substantially, not all errors were eliminated. There are two possible reasons for this. First, patient-safety technology is effective only if it is used as intended. Even though the study hospital expended substantial resources in the training of end users, 20% of the drugs administered on units with the bar-code eMAR technology were given without the bar-code scanning step during the study period; this rate of noncompliance might be due in part to the learning curve in the early stages of implementation. Second, the study hospital used an early version of the software; several important improvements have been incorporated since this study was carried out, including improved functionality for intravenous medication administration, sliding-scale dosing, fractional dosing, and nonstandard scheduling of doses. These issues illustrate that the deployment of health information technology should be thought of not as a single event in time but rather as an iterative process that requires modifications and improvements.

This study has several limitations. First, the results reflect the experience of one hospital that already has fully implemented computerized phy-

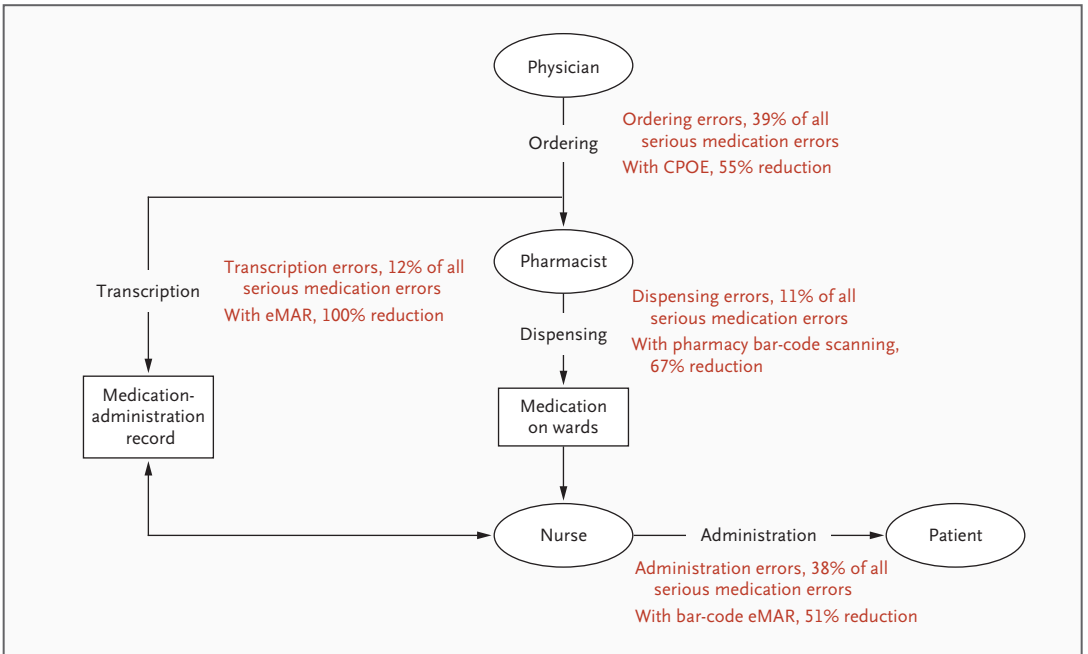

Figure 1. Effect of Health Information Technology at Key Stages in the Process of Medication Use.

Data on errors during the four phases of medication use are from Leape et al.[3] The percent reduction in ordering errors with the use of computerized physician-order entry (CPOE) is from Bates et al.[7] The percent reduction in dispensing errors with bar-code scanning in the pharmacy is from our previous study.[8] The percent reduction in medication-administration errors with the bar-code eMAR technology and the percent reduction in transcribing errors are from the current study.

sician-order entry for physicians and bar-code verification for pharmacy staff. Hospitals that choose to implement the bar-code eMAR technology without computerized physician-order entry, pharmacy bar-code verification, or both may find that it has a different effect on administration errors. For example, hospitals without computerized physician-order entry will probably not eliminate transcription errors. Second, the study examined potential adverse drug events, not actual adverse drug events. Although an earlier study estimated that one actual adverse drug event occurs for every seven potential events,[30] further research will be needed to determine the true effect of the bar-code eMAR on adverse drug events. Third, the study hospital designed the application in close collaboration with users and clinical leaders who were willing to support a substantial change in workflow to improve the overall medication process. In addition, extensive resources were expended to support the rollout, including adequate training, onsite support, adequate hardware, and a responsive software-development team. Organizations interested in implementing the bar-code eMAR should consider these factors in order to maximize their investment in this patient-safety technology, and future studies should evaluate vendor solutions implemented in the community setting. Fourth, the nurses observed in this study might have performed better because they were being watched (a phenomenon known as the Hawthorne effect); however, this effect probably applied equally to observations made or units with and without bar-code eMAR technology. Previous studies have also suggested that the Hawthorne effect is minimal after the subject is initially exposed to the observer.[31] Fifth, even though observations were made simultaneously on the units with the bar-code eMAR and on those without it for part of the study period, the staggered rollout schedule meant that more observations were made on units without the bar-code eMAR during the early part of the study period. Our findings might therefore have been subject to a secular effect, although it is unlikely that this effect would have been substantial over a period of 9 months.

Taken together, our findings show that the bar-code eMAR technology improves medication safety by reducing administration and transcription

errors, providing support for the inclusion of this technology as a 2013 criterion for achieving meaningful use under the American Recovery and Reinvestment Act. Given challenges in implementing this technology, however, further research should focus on identifying factors that will lead to its optimal implementation.

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Effect of warning symbols in combination with education on the frequency of erroneously crushing medication in nursing homes: an uncontrolled before and after study

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ABSTRACT

Objectives: Residents of nursing homes often have difficulty swallowing (dysphagia), which complicates the administration of solid oral dosage formulations. Erroneously crushing medication is common, but few interventions have been tested to improve medication safety. Therefore, we evaluated the effect of warning symbols in combination with education on the frequency of erroneously crushing medication in nursing homes.

Setting: This was a prospective uncontrolled intervention study with a preintervention and postintervention measurement. The study was conducted on 18 wards (total of 200 beds) in 3 nursing homes in the North of the Netherlands.

Participants: We observed 36 nurses/nursing assistants (92% female; 92% nursing assistants) administering medication to 197 patients (62.9% female; mean age 81.6).

Intervention: The intervention consisted of a set of warning symbols printed on each patient's unit dose packaging indicating whether or not a medication could be crushed as well as education of ward staff (lectures, newsletter and poster).

Primary outcome measure: The relative risk (RR) of a crushing error occurring in the postintervention period compared to the preintervention period. A crushing error was defined as the crushing of a medication considered unsuitable to be crushed based on standard reference sources. Data were collected using direct (disguised) observation of nurses during drug administration.

Results: The crushing error rate decreased from 3.1% (21 wrongly crushed medicines out of 681 administrations) to 0.5% (3/636), RR=0.15 (95% CI 0.05 to 0.51). Likewise, there was a significant reduction using data from patients with swallowing difficulties only, 87.5% (21 errors/24 medications) to 30.0% (3/10) (RR 0.34, 95% CI 0.13 to 0.89). Medications which were erroneously crushed included enteric-coated formulations (eg, omeprazole), medication with regulated release systems (eg, Persantin; dipyridamol) and toxic substances (eg, finasteride).

Conclusions: Warning symbols combined with education reduced erroneous crushing of medication, a well-known and common problem in nursing homes.

Strengths and limitations of this study

- An innovative and feasible intervention consisting of warning symbols in combination with education reduced erroneous crushing of medication in nursing homes.
- Information on whether medication may be crushed was available at the stage of medication administration.
- The study design (an uncontrolled before and after study) means that we could not control for other factors potentially influencing the error rate.

INTRODUCTION

Nursing home residents often receive a large number of medicines.[1 2] A considerable proportion of residents have difficulty swallowing (dysphagia), which complicates the administration of solid oral dosage formulations.[3] Often, dose form modifications such as crushing tablets or opening capsules are done to administer medications. However, crushing formulations with special coatings or regulated release systems may result in subtherapeutic (crushing coatings) or toxic (crushing regulated-release systems) blood concentrations of the medicines causing adverse events. Furthermore, medications containing substances such as cytotoxic agents should not be crushed as small particles may harm the person handling the administration.[4 5] Recent studies in nursing homes suggest that between 0.5% and 10%

of medications are erroneously crushed,[4 6–9] although this type of error seemed to be uncommon/absent in two other studies.[10 11]

Few studies have investigated interventions to reduce medication administration errors and most of these studies have been carried out in the hospital setting.[12–14] Little is known about interventions to reduce the rate of erroneously crushing formulations in nursing homes. In a study in Dutch nursing homes, Stuijt *et al*[9] showed that a multifaceted intervention including education and a computerised system alerting staff to patients with swallowing difficulties was effective in reducing the frequency of wrongly crushed medication, but an error rate of about 3% was still observed. In a study in Belgian nursing homes, an educational intervention including information on crushing of medication eliminated erroneous crushing.[6] More research is needed to develop interventions to improve medication safety in the nursing home setting. Warning symbols in combination with education are widely used in healthcare to promote safety-appropriate behaviour.[15] To the best of our knowledge, it has not been tested whether warning symbols can be used to reduce crushing errors. Therefore, we evaluated the effect of warning symbols in combination with education on the frequency of erroneously crushing medication in nursing homes.

METHODS

Design and setting

This was a prospective uncontrolled intervention study with a preintervention and postintervention measurement. The study was conducted on 18 wards (8–10 beds/ward, total of 200 beds) in three nursing homes in the north of the Netherlands. Patients were cared for by elderly care physicians, nurses, nursing assistants and volunteers. Electronic medical records and electronic prescribing systems were used in all institutions. Medication was supplied weekly by one hospital pharmacy as unit dose packages. Pharmaceutical services provided by pharmacists included daily computerised monitoring of all new prescriptions (eg, to detect drug–drug interactions) as well as regular multidisciplinary medication reviews of all patients. Nurses and nursing assistants were responsible to administer medication to residents. Administrations were recorded on the medication charts. In case patients had dysphagia and were prescribed medication they could not swallow, nurses contacted the prescriber or pharmacist to ask for a suitable alternative formulation (eg, liquid formulation) or nurses crushed medication.

The study was not reviewed by a medical ethics committee as, according to Dutch regulation, approval of the medical ethics committee was not required as there was no direct interaction with patients and patient data were anonymised (Dutch Medical Research Involving Human Subjects Act).[16] Moreover, the intervention was part of an ongoing initiative for quality improvement and not put in place for the purpose of the study. Ward supervisors and management approved the study.

Intervention

The intervention consisted of the following four elements:

- Warning symbols printed on the unit dose sachets produced by the automatic tablet dispensing and packaging system. Two symbols were chosen, a positive symbol indicating that a tablet or capsule could be crushed and a negative symbol indicating that this could not be done. The symbols were added to the description line of each medication on the sachets (figure 1A, B). These were introduced on 1 February 2014. The information whether medication could be crushed or not was gathered by SvW, LW and TB based on standard reference sources.[17 18] We chose a positive and a negative symbol to give nurses complete information including confirmation on which medication they were allowed to crush. In this way, we ensured that medication without a symbol (eg, medication where suitability of crushing had not been assessed yet) looked different. Technical limitations of the software of the unit dose dispensing system restricted the size and the choice of warning symbols which could be printed on the sachets. Pictograms in the form of pictures as developed by the Pharmacopeial Convention of the USA could not be used.[19] We had to choose relatively simple symbols and could not add any colour.
- A 20 min lecture given by a pharmacist (LW or TB) to nurses and nursing assistants on each study ward in January and February 2014. It covered information on drug formulations which should not be crushed and informed staff on alternatives as well as explaining the introduction of the new symbols. Overall, 77 nurses and nursing assistants out of 160 (48%) attended the lectures, about 4 per ward.
- A newsletter sent digitally to all nursing home staff in February 2014, summarising the content of the lecture on one page. This was a special edition of the quarterly newsletter of the hospital pharmacy. The newsletter was written by SvW, LW and TB.
- A poster explaining the meaning of the two symbols and emphasising that nursing staff should contact the physician or pharmacy department for patients with dysphagia who were prescribed medication which could not be crushed. The poster was introduced during the lectures. Nursing staff were advised to place the poster on the wards as a reminder. The poster was written by SvW, LW and TB.

We chose the three different educational approaches (lecture, newsletter and poster) to maximise the number of staff we could reach. Furthermore, these approaches were commonly used in our study setting (and also in other nursing homes), which increased the feasibility of the study and the applicability in other settings.

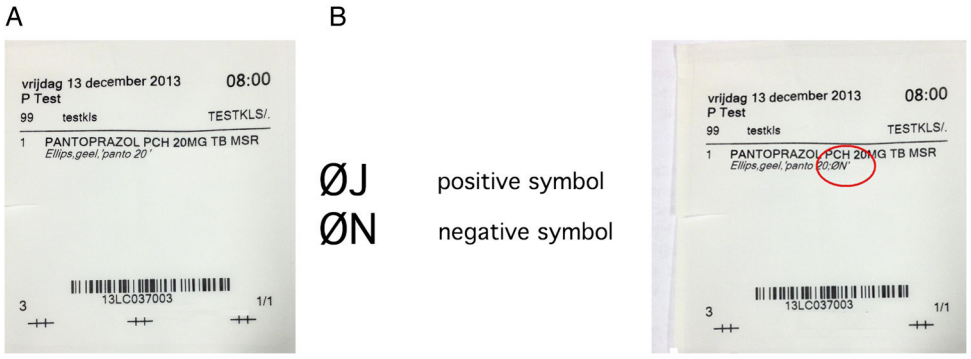

Figure 1 (A) An example of the unit dose sachet before introduction of the warning symbol. (B) Explanation of the two warning symbols. Positive symbol: formulation may be crushed (J as short for ja=yes); negative symbol: formulation may not be crushed (N as short for nee=no); right: example of the unit dose sachet including the warning symbol.

Data collection

Data were collected using the disguised observation method, recognised as a valid and reliable method (gold standard) to detect medication administration errors[20] and suitable to be used to evaluate interventions.[12 21–23] In the current study, we have used the same approach as in our previous studies on medication administration errors,[24] with essential elements comprising careful training of the observer and a consistent use of the definition of a crushing error. Ward staff were told that the observer was attending the medication rounds to get a general idea of the medication administration process as part of his hospital placement. Data were collected by one pharmacy student (author SvW), trained in observation technique including a 3-day test period on different wards. The observer asked each participating nurse/nursing assistant for permission to observe prior to the medication round. Sex and level of education (ie, qualified nurse or nursing assistant) were noted. He then accompanied staff during the medication rounds, observing all medication administrations to the patients. It was agreed that the observer should intervene in case he became aware of a potentially serious medication administration error, but this was not the case. The observer made a mental note of all medications which were crushed by nursing staff and recorded this information on paper immediately after leaving the ward.

After the drug round was completed, the observer retrieved data on observed patients and all medication administrations of oral solid dosage forms (ie, tablets and capsules) from the computerised pharmacy information system and entered this in Excel MS (Microsoft Corp., Redmond, Washington). Data comprised: name of the nursing home, type of ward, date and time of drug round, sex and age of the patient and medication details (number of medications administered during the observed drug round). For all medications which were crushed, full medication details (name and dose) were retrieved. SvW de-identified all patient information retrieved from the pharmacy information system.

Data were collected in November–December 2013 (preintervention period) and March 2014 (postintervention period). One medication round was observed on each ward in each period. The morning drug administration round (07:00–10:00) was selected as the majority of medications were administered during this round. Data collection was carried out on 18 consecutive weekdays each period, excluding weekends.

We defined a crushing error as the crushing of oral solid dosage forms considered unsuitable to be crushed according to Dutch standard references. We used two sources, a handbook by hospital pharmacists and the electronic database of the Royal Dutch Pharmaceutical Society.[17 18] Both sources are based on consensus of professionals. We chose the sources to ensure that we include cases which have been judged to be clinically relevant, that is, crushing potentially leading to changes in pharmacological response due to destroyed coating or regulated release systems or crushing of formulations containing toxic substances potentially harming staff handling the administration. The observer analysed the data and this was independently checked by two qualified pharmacists (TB and LW).

Main outcome measure

The main outcome was the relative risk (RR) of crushing errors in the postintervention compared to the preintervention period.

Sample size

On the basis of previous studies of crushing errors,[4 6–9] we assumed a rate of 3% wrongly crushed medication. Although using different interventions, previous studies showed considerable reductions in crushing error rates,[6 9] so we expected to see a 66% reduction by the intervention. Overall, 500 medication administrations needed to be observed to be able to indicate a significant reduction (α=0.05; power of 0.08). It was estimated that 15 wards of about eight patients needed to be included.

Analysis

Categorical data were compared by performing a χ^2 test, while means were compared by performing Student's t-test. Data were analysed using SPSS V.20.0.0.2 (SPSS, Chicago, Illinois, USA). We calculated the percentage of erroneously crushing medication by dividing the number of crushing errors by the number of observed solid oral doses as has been done in previous studies.[6 9 14] We also calculated the error rate by dividing the number of crushing errors by the number of medications which should not have been crushed in patients with swallowing difficulties. We determined the RR and 95% CI of erroneous crushing occurring after the intervention.

RESULTS

We observed 36 nurses/nursing assistants (92% female; 92% nursing assistants) administering medication to 197 patients (62.9% female; mean age 81.6). The groups of the preintervention and postintervention measurement were partly the same. There was no statistical difference between general characteristics of patients and the nursing staff of the preintervention and postintervention measurement (table 1).

We observed 681 medication administrations to 164 patients preintervention and 636 medication administrations to 150 patients postintervention. The number of patients who had their medication crushed decreased from 19 (11.6%) to 11 (7.3%) (p=0.20). These patients received 24 (preintervention period) and 10 (postintervention period) medications which should not be crushed.

We observed 21 crushing errors before and 3 crushing errors after the intervention. There was a significant decrease of erroneously crushing medication from 3.1% to 0.5% (RR 0.15 (95% CI 0.05 to 0.51) using the denominator of all observed doses. Likewise, there was a significant reduction using data from patients with swallowing difficulties only, 87.5% (21 errors/24 medications) to 30.0% (3/10) (RR 0.34, 95% CI 0.13 to 0.89). Medications which were erroneously crushed included enteric-coated formulations (eg, omeprazole), medication with regulated release systems (ie, Persantin; dipyridamol) and toxic substances (eg, finasteride). Erroneous crushing was observed on 11 out of the 18 wards (61%) preintervention and 3 out of the 18 wards (17%) postintervention. Error rates per ward can be found in online supplementary appendix 1.

DISCUSSION

We observed a significant reduction in the rate of erroneously crushing medication after introducing warning symbols combined with education. The strength of our intervention was that information on crushing was available at the stage of administration at the point when nursing staff have to make a decision on how to give the medication to the patient. Technical limitations of the software of the unit dose dispensing system meant that we had to choose relatively simple symbols and could not add any colour. Our symbols could be improved by adapting one of the existing pharmaceutical pictograms which should be further tested to ensure comprehension.[15] We gave lectures, distributed posters and sent a newsletter to combine the warning symbol with education to remind staff about inappropriate crushing and ensure comprehension of the symbols.

Within medication error research, an important choice is the way of calculating the medication error rate.[20 25] We calculated the crushing error rate by dividing the number of crushing errors by the total number of observed solid oral dosage forms. This is in line with previous studies on crushing errors[6 9 14] and studies on medication administration errors in general.[20 24] We therefore chose this method to allow for comparison with the literature. In fact, our error rate was within the range of previous studies. An alternative way to calculate the error rate was to divide the number of crushing errors by the number of medications which should not

Table 1 Characteristics of participating nursing staff and patients

	Preintervention	Postintervention	p Value
Total number of nursing staff	20	20	
Number of female nursing staff (percentage of all nursing staff)	18 (90)	19 (95)	0.548*
Number of nursing assistants (percentage of all nursing staff)	19 (95)	18 (90)	0.548*
Total number of patients	164	150	
Number of female patients (percentage of all patients)	106 (64.6)	99 (66.0)	0.800*
Mean age of patients	81.7	81.5	0.893†
Nursing home A—number of patients (percentage of all patients)	40 (24.4)	37 (24.7)	0.667*
Nursing home B—number of patients (percentage of all patients)	63 (38.4)	64 (42.7)	
Nursing home C—number of patients (percentage of all patients)	61 (37.2)	49 (32.7)	
Mean number of observed oral solid medications per patient/observed drug round	4.15	4.24	0.761†

*χ^2 test.
†Student's t-test.

have been crushed in patients with swallowing difficulties. This also showed a significant decrease of the error rate supporting our conclusions. The second way of determining the error rate is less likely to be influenced by changes in medication use patterns.

We recommend wider implementation of the warning symbols in nursing homes. However, this depends on the use of unit dose dispensing systems and technical possibilities to add warning symbols on the sachets. Furthermore, it is important to have a service in place providing information on alternative medications for patients. An advantage is a good relationship between the pharmacy department and the nursing home staff like we have in our setting.[26] Nurses were advised to contact the prescriber or the pharmacist to discuss alternatives (eg, liquid formulations) for patients with swallowing difficulties. Our computer system used for electronic prescribing also provided the possibility for physicians and nursing staff to document swallowing difficulties in the medication records. The pharmacist could then select alternative formulations before dispensing medication to the ward. Full implementation of documentation of dysphagia in the electronic records may be the next step in reducing crushing errors further. Stuijt *et al*[9] have already shown that this is a successful strategy in reducing crushing errors.

Our study has several limitations. First, we used a before and after study design without including a control group. It was impossible to include a control group in our own setting as there was only one machine available to supply the unit doses. Technically, all wards had to receive the same unit doses (all with or without symbols). However, we are not aware of any changes taking place in the nursing homes during the intervention period which may have influenced the crushing error rate. Second, some limitations need to be discussed concerning the disguised observation technique. The presence of an observer may have an effect on behaviour of nursing staff, but this effect has been shown to be relatively limited.[21] The observer was carefully trained in the observation technique. As a research group, we have ample experience with observation-based research.[22 23 27] The observer took 'mental notes' of medication which had been crushed and recorded these instances straight after completing observation of each drug round. We chose this method, as taking notes during observation may be regarded as obtrusive and raise suspicion about the true nature of the study. There were only few doses which were crushed in each drug round, so it was easy to remember these instances correctly. All details of the administered medication were retrieved from the electronic-dispensing records available in the pharmacy department. Furthermore, it is important to note that the observer was not involved in any of the educational activities, so nursing staff were not aware of a link between the observer and the intervention. Unfortunately, we could not keep the observer blind. Being aware of the nature of the intervention theoretically could have introduced some bias in the data collection and analysis. However, since the definition of a crushing error was based on clear guidelines and assessment was independently checked and confirmed by two pharmacists, we think that this effect is negligible. Third, we did not assess the clinical significance of the observed errors.[28] Anecdotal evidence would suggest that serious adverse events occur rarely,[4 29] so more research is needed to study the cost-effectiveness of our intervention. A final limitation is that we investigated neither the contribution of each 'ingredient' of our intervention separately nor the long-term effect of our intervention. On the basis of theoretical grounds, we believe that a warning symbol should be accompanied by education to ensure comprehension.[15] We did not assess the overall proportion of staff we reached with our educational activities. A reasonable number of staff attended the lectures (about 4 members of staff of each study ward, in total 77 out of 160 eligible members of staff, 48%). It remains a challenge to distribute information effectively to all members including part time and temporary staff.

In our study, we used relatively traditional ways of disseminating the information on our innovation. Future studies could explore alternative approaches such as social media. Although we did not assess this as part of our trial, repeated educational efforts are probably necessary for a sustained effect. We also recommend to further develop easy to understand warning symbols/pictograms using colour, for example, red for not crushing, green for crushing using established guidelines.[30] In summary, continuous education, improved symbols and the documentation of dysphagia problems in medical records may be a way to reduce the crushing error rate further. Finally, we hope to inspire others to use warning symbols or pictograms to improve patient safety following promising examples from patient education.[31 32]

CONCLUSION

Warning symbols combined with education reduced erroneous crushing of medication, a well-known and common problem in nursing homes. Wider implementation of this intervention could improve patient safety.

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