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CHIARA ERMINIA DA ROCHA

SISTEMA DE SUPORTE À DECISÃO CLÍNICA PARA
INTERVENÇÕES FARMACÊUTICAS NA PRÁTICA DA
AUTOMEDICAÇÃO RESPONSÁVEL

ARACAJU

2014

CHIARA ERMINIA DA ROCHA SISTEMA DE SUPORTE À DECISÃO CLÍNICA PARA INTERVENÇÕES FARMACÊUTICAS
NA PRÁTICA DA AUTOMEDICAÇÃO RESPONSÁVEL 2014

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Tese apresentada ao Núcleo de Pós-Graduação em
Medicina da Universidade Federal de Sergipe como
requisito parcial à obtenção do grau de Doutora em
Ciências da Saúde.

Orientador: Prof. Dr. Divaldo Pereira de Lyra Júnior

Co-orientador: Prof. Dr. Celso Satoshi Sakuraba

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"Enquanto estiver vivo, sinta-se vivo. Se sentir saudades do que fazia, volte a fazê-lo. Não viva de fotografias amareladas... Continue, quando todos esperam que desistas. Não deixe que enferruje o ferro que existe em você. Faça com que em vez de pena, tenham respeito por você. Quando não conseguir correr através dos anos, trote. Quando não conseguir trotar, caminhe. Quando não conseguir caminhar, use uma bengala. Mas nunca se detenha"

Madre Teresa de Calcuta

RESUMO

SISTEMA DE SUPORTE A DECISÃO CLÍNICA PARA INTERVENÇÕES FARMACÊUTICAS NA PRÁTICA DA AUTOMEDICAÇÃO RESPONSÁVEL.

Chiara Erminia da Rocha. Universidade Federal de Sergipe, Núcleo de Pós-Graduação em Medicina, Aracaju, 2014.

Objetivo: desenvolver sistema de suporte à decisão clínica dos farmacêuticos no manejo de sintomas menores (SM) com medicamentos isentos de prescrição (MIPs). **Métodos:** Inicialmente, foi realizada uma revisão sistemática, entre janeiro 1980 a agosto de 2010, nas bases de dados Medline/Pubmed, Scopus, Lilacs e Embase. Posteriormente, uma amostra de conveniência de farmacêuticos comunitários (FC) participou de uma entrevista semi-estruturada realizada nas farmácias comunitárias de duas grandes redes em Aracaju, no período de Junho a Agosto de 2012. Em seguida, a metodologia do paciente simulado (PS) foi aplicada a mesma amostra de FC com dois casos de SM (1 - mulher adulta com sinusite; 2 - mulher grávida com tosse seca e dor nas costelas). As simulações foram avaliadas de acordo com o instrumento desenvolvido pela Farmacopéia dos Estados Unidos (USP) chamado "Medication Counseling Behavior Guidelines" e validado para o português. No período de fevereiro de 2012 a janeiro de 2014, foi desenvolvido um *software* para auxiliar o farmacêutico no processo de manejo de SM do trato respiratório com MIPs. Para tanto, 7 farmacêuticos clínicos, juntamente com engenheiros de produção, determinaram o conteúdo dos algoritmos. **Resultados:** Apenas nove artigos preencheram todos os critérios de inclusão estabelecidos na revisão sistemática. Foi observado que quatro estudos relataram adesão do paciente a orientação do farmacêutico. Participaram da entrevista 40 FC e destes, 62,9% não cursaram na graduação disciplina sobre o manejo de SM. As respostas dos FC sobre sua atitude frente a automedicação, revelou que a depender do tempo da queixa eles indicam um tratamento ou encaminham o paciente ao médico. Foram realizadas 80 simulações que apresentaram um tempo total de atendimento farmacêutico de 91,31 segundos (DP \pm 68,63). A análise das simulações revelou que 83,3% e 72,5% dos FC recomendaram a visita ao médico para o PS1 e para o PS2, respectivamente. Foi observado que 45% e 17% dos FC revisaram a solicitação do paciente antes da orientação. No processo de desenvolvimento do *software*, os farmacêuticos especialistas apontaram que os algoritmos deveriam explorar as características dos SM (início, frequência, duração), os tratamentos farmacológicos e não-farmacológicos apropriados e os parâmetros de encaminhamento do paciente ao médico. A versão final do *software* proporciona a determinação de diagnóstico condizente com o conjunto de sinais e sintomas do paciente, retornando ao farmacêutico uma pequena lista das possíveis enfermidades. **Conclusão:** O *software* poderá melhorar as condições de trabalho dos farmacêuticos comunitários, adicionando-lhes maior evidência científica no manejo de SM com MIPs.

Descritores: farmacêutico comunitário; sintoma menor; automedicação responsável; medicamentos isentos de prescrição; software.

ABSTRACT

A CLINICAL DECISION SUPPORT SYSTEM FOR PHARMACIST INTERVENTION ON THE PRACTICE OF RESPONSIBLE SELF MEDICATION

Chiara Erminia da Rocha. Universidade Federal de Sergipe, Núcleo de Pós-Graduação em Medicina, Aracaju, 2014.

Objective: to develop a clinical decision support system for pharmacist intervention on minor illness (MI) with non prescription medicines (NPM). **Methods:** Initially, a systematic review was performed using the articles published between January 1980 and August 2010, using the Medline / Pubmed, Scopus, Embase, and Lilacs. Subsequently, a convenience sample of community pharmacists (CP) participated in a semi-structured interview conducted in two major networks community pharmacies in Aracaju, between June and August 2012. Then the methodology of simulated patient (SP) was applied to the same sample of pharmacists with two cases of SM (1 - an old woman with sinusitis; 2 – a pregnant woman with dry cough and pain in the ribs). The simulations were evaluated according to the instrument developed by the United States Pharmacopeia (USP) called "Medication Counseling Behavior Guidelines "and validated for the Portuguese. From February 2012 to January 2014, a software was developed to assist the pharmacist in the management of Lower respiratory tract symptoms with medicines. To this end, 7 clinical pharmacists, along with production engineers determined the content of algorithms. **Results:** Only nine papers met all inclusion criteria in the systematic review. It was also noted that only four studies reported patient adherence to pharmacist intervention. Attended the interview 40 CP and of these, 62.9% of CP had not MI management when they graduated. The responses from pharmacists about their attitude toward self-medication revealed that depending on the time of the complaint they indicate a treatment or refer the patient to the doctor. 80 simulations were performed and showed an average time spent on counselling the SP of 91.31 seconds (SD \pm 68.63). The analysis of the simulations demonstrated that 83.3% and 72.5% of CP recommended a visit to the doctor in SP1 and SP2, respectively. It was observed that 45% and 17% of the CP reviewed the patient's request before orientation. In software development process, the clinical pharmacist pointed out that the algorithms should explore the characteristics of the MI (onset, frequency, duration), the appropriate pharmacological and non- pharmacological treatments and forwarding parameters of the patient to the doctor. The final version of the software provides the determination of consistent diagnosis based on the set of signs and symptoms of the patient, returning to the pharmacist a short list of possible diseases. **Conclusion:** The software could improve the conditions of CP work by adding greater scientific evidence in managing MI with NPM.

Keywords: Community pharmacist, minor illness, responsible self-medication, non prescription medicines; software.

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LISTA DE ABREVIATURAS

<i>Community pharmacist</i>	CP
<i>Community pharmacists</i>	CPs
Diagnóstico Farmacêutico de Sintomas Menores	DFSM
Farmacêutico comunitário	FC
Farmacêuticos comunitários	FCs
Intervenção farmacêutica	IF
Intervenções farmacêuticas	IFs
Medicamento não prescrito	MNP
Medicamentos não prescritos	MNPs
<i>Medication Counseling Behavior Guidelines</i>	MCBG
<i>Minor illness</i>	MI
<i>Non prescription medicine</i>	NPM
<i>Non prescription medicines</i>	NPMs
Paciente simulado	PS
Pacientes simulados	PSs
<i>Pharmacist intervention</i>	PI
<i>Pharmacist interventions</i>	PIs
Sintoma menor	SM
Sintomas menores	SMs

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1. INTRODUÇÃO

No último século, os medicamentos foram um dos principais responsáveis pelo aumento da expectativa de vida da população mundial (LLIMÓS, 2005). Em contraste, Llimós e Faus (2003) afirmam que problemas relacionados aos medicamentos são fatores de risco à saúde, tão perigosos quanto: alcoolismo, sedentarismo, tabagismo, etc. Nos Estados Unidos, por exemplo, o custo das doenças relacionadas à farmacoterapia triplicou nos últimos anos e ultrapassou os US\$ 177 bilhões (ERNST et al., 2001; ROTTENKOLBER et al., 2011). Em consequência, a morbimortalidade relacionada aos medicamentos já é reconhecida como um problema de saúde pública, contribuindo de maneira importante com o incremento das internações hospitalares (VIEIRA, 2007).

O autocuidado é definido como a capacidade dos indivíduos, famílias e comunidades em promover e manter a saúde, prevenir e lidar com a incapacidade oriunda da doença, com ou sem o apoio de um profissional de saúde (WHO, 2009). Neste sentido, é um conceito amplo que contempla práticas de higiene, alimentação, estilo e hábitos de vida, fatores socioeconômicos e a automedicação (WHO, 1998). Esta é definida como o uso de medicamentos por parte dos indivíduos para tratar distúrbios e aliviar sintomas autodiagnosticados, ou se refere ao uso intermitente ou contínuo de um medicamento prescrito por um médico para doenças crônicas ou recorrentes ou sintomas (WHO, 2000; AWAD et al., 2005; FIP, 2013; WHO, 2013). A automedicação é considerada responsável quando o manejo das queixas for realizado com medicamentos que poderão vir a ser eficazes e seguros caso sejam utilizados seguindo as orientações fornecidas pelo farmacêutico (WHO, 2013).

Na prática, o autocuidado e a automedicação são responsabilidade do paciente, à medida que o mesmo seleciona o medicamento a ser utilizado para o tratamento ou alívio dos agravos à saúde quando não há contato com o farmacêutico (YOUSEF et al., 2008). Além do acesso fácil e do baixo custo dos medicamentos que não requerem prescrições, a que se soma a reduzida oferta de serviços de saúde e disponibilidade quando deles se necessita, os meios de comunicação de massa constituem um dos principais fatores que estimulam a automedicação, aumentando os riscos advindos desta prática (KLEMENC-KETIS et al., 2011). Em contrapartida, é necessário que o paciente receba informações adequadas que subsidiem a escolha do medicamento que cause menos riscos à saúde (PORTEOUS et al., 2006; SWEILEH et al., 2010). Desde 1998, a Organização Mundial da Saúde (OMS) preconiza que a automedicação responsável é prática determinante para o autocuidado, visto que o

farmacêutico, quando presente, se responsabiliza pela provisão de informações ao paciente, possibilitando que o mesmo venha a efetuar a escolha do medicamento mais indicado, efetivo, seguro e conveniente.

Faz-se mister que o consumo dos medicamentos não prescritos conte sempre com a participação dos profissionais de saúde, sejam médicos, sejam farmacêuticos, visto que esses produtos podem estar incriminados com a possibilidade de demandar admissões hospitalares decorrentes de problemas farmacoterapêuticos preveníveis (PIRMOHAMED, 2004; LEENDERTSE, 2008). Estudos demonstram que os consumidores de analgésicos isentos de prescrição não sabem como utilizá-los e desconhecem seus efeitos indesejáveis (WILCOX et al., 2005; STOSIC et al., 2011). Além disso, há casos de intoxicações por esses medicamentos, particularmente, o paracetamol responsável por cerca de 150 mortes/ano no Reino Unido (HAWTON et al., 1996). É digno de nota que, no Brasil, não existem dados disponíveis sobre a intoxicação provocada por medicamentos não prescritos contendo paracetamol em sua formulação.

Em 2007, os gastos públicos com medicamentos não prescritos na União Européia foram da ordem de 25,9 bilhões de euros (AESGP, 2012). Assim sendo, os medicamentos não prescritos ocupam lugar de destaque nas práticas profissionais e de autocuidado do paciente, como por exemplo, na automedicação, que pode estar relacionada com a promoção, manutenção e recuperação da saúde, além da prevenção de doenças. Contudo, a sua utilização é motivo de preocupação social constante, devido ao fácil acesso da população (COOPER, 2013). Assim, medidas de restrição à venda de medicamentos que apresentam risco potencial à saúde devem ser implementadas, a fim de promover maior segurança ao paciente (ROUMIE et al., 2004; FENDRICK et al., 2008; STOSIC et al., 2011; BADIGER et al., 2012; BRABERS et al., 2013). Ademais, propõe-se a adoção de sistemas de monitoramento junto aos médicos e farmacêuticos a fim de que realizem a triagem do quadro clínico do paciente, avaliem a necessidade de ser feita uma consulta médica efetivando, se for o caso, a dispensação de medicamentos que promova o seu uso racional (BADIGER et al., 2012).

O número de medicamentos não prescritos disponíveis no mercado possibilitou que a inserção do farmacêutico comunitário no manejo de sintomas menores nos últimos anos, crescesse em todo o mundo, tornando essa prática mais responsável (GLOVER et al., 2008). Além disso, o farmacêutico está habilitado a informar e orientar o paciente na dispensação, selecionando, criteriosamente, o medicamento mais adequado, avaliando a necessidade da sua utilização e contribuindo para a melhoria da qualidade de vida do paciente (PARMLEY,

2000; SOARES, 2002). Assim, a preocupação com a segurança do paciente, no cenário atual, é uma das prioridades dos serviços de saúde (FERRER-LÓPEZ et al., 2007; BRASIL, 2013b).

Nesse quadro, a automedicação responsável consiste precipuamente na orientação para o manejo de medicamentos não prescritos voltados para o tratamento de doenças menores (enfermidades agudas, de baixo período de latência e autolimitadas¹) (PARMLEY, 2000; SOARES, 2002). Segundo a Agência Nacional de Vigilância Sanitária (Anvisa) (2003), esses medicamentos deveriam ser usados como qualquer medicamento, de forma segura, de acordo com as instruções da bula, não necessitando de orientação de profissionais de saúde e nem da apresentação da receita médica na sua aquisição. Todavia, fatores como a baixa escolaridade e os déficits cognitivos, preponderante no grupo de idosos, influenciam diretamente na compreensão das informações e requerem suporte do farmacêutico (LUBINGA et al., 2011; YOU et al., 2011; BRABERS et al., 2013).

Em 1998, a OMS e a Federação Internacional de Farmacêuticos publicaram, conjuntamente, um documento que definiu o papel do farmacêutico no autocuidado e na automedicação. Este documento apontou, entre seus objetivos a detecção dos principais sintomas menores que acometem a população e a elaboração do perfil das práticas de automedicação e do autocuidado que devem ser usadas no seu tratamento, destacando suas vantagens, desvantagens e os seus limites, identificando das responsabilidades, mecanismos éticos e da regulamentação das funções do farmacêutico junto aos usuários, prescritores e a indústria farmacêutica.

Neste contexto, o desenvolvimento de protocolos clínicos ajuda o farmacêutico no processo de tomada de decisão em resposta a um sintoma, na indicação de medicamentos não prescritos e na identificação de situações de risco à saúde que necessitem de diagnóstico médico ou de outros cuidados em saúde (AL-EIDAN et al., 2000; MOHAN et al., 2003). Segundo Vella (2009), o protocolo consiste de um algoritmo baseado em evidência aplicado na terapia de uma condição clínica que se inicia com um diagnóstico confirmado para determinada doença e conduz o profissional de saúde para as melhores opções disponíveis para os pacientes.

O protocolo permite a mensuração do impacto da intervenção farmacêutica e a melhora da condição clínica do paciente. Contudo, é essencial que o farmacêutico comunitário possua habilidades na área da comunicação e competências na área clínica (boas práticas de

¹ Aquelas que promovem uma reação com sinais ou sintomas, em grau maior ou menor de evidência clínica, via de regra possibilitando um auto-tratamento, tendendo, pois a serem autolimitadas tendo, via de regra curta duração.

prescrição, fisiopatologia, semiologia, farmacologia clínica e terapêutica), uma vez que somente o protocolo não suprirá a carência a que fizemos alusão (AZZOPARDI, 2000; VELLA et al., 2009; BRASIL, 2013a). A qualificação nos aspectos para os quais chamamos a atenção são relevantes para dar conta das necessidades dos pacientes quanto ao tratamento de sintomas menores com medicamentos não prescritos e para desenvolver a automedicação responsável (RUTTER et al., 2004). Isto requer do profissional uma preparação que contemple, igualmente, programas de educação continuada para aquisição ou aprofundamento de habilidades de comunicação e clínicas (GALATO et al., 2009).

No Brasil, o Conselho Federal de Farmácia, ao aprovar as resoluções 357/2001 499/2008, incluiu nas mesmas, avanços da prática profissional, no que diz respeito à automedicação responsável. Recentemente, a publicação das Resoluções 585/2013, que trata das atribuições clínicas do farmacêutico, e a 586/2013, que trata do ato da prescrição farmacêutica, legalizaram a prática da automedicação responsável (BRASIL, 2013). No entanto, a falta de formação específica dos farmacêuticos e a necessidade de instrumentos adequados, como pictogramas e algoritmos de tomada de decisão contribuem para a geração de receios entre os farmacêuticos no que tange à insegurança, nele remanescente, para dar conta do manejo de queixas clínicas, assim como da farmacoterapia.

A prática da automedicação responsável trás vantagens para os serviços públicos de saúde ao diminuir a demanda por cuidados médicos e, para o farmacêutico, pela possibilidade oferecida para que ele faça uso das suas habilidades clínicas (HUGHES et al., 2009; VELLA et al., 2009). No entanto, segundo Major et al. (2010), a habilidade dos farmacêuticos para orientar os pacientes sobre a escolha da melhor alternativa terapêutica depende do cuidado prestado, do entendimento e aceitação do diagnóstico pelo paciente, além da necessidade de adesão à terapêutica.

Baseado nestes pressupostos, os farmacêuticos precisam ser capacitados e encorajados a realizar questionamentos estruturados para o paciente (a fim de obter informações clínicas relevantes), prover orientações baseadas em evidência sobre os sintomas menores apresentados e o medicamento não prescrito selecionado, bem como acompanhar o efeito da intervenção farmacêutica proposta (MEHUYS et al., 2009).

Ante ao exposto, é necessário investir em pesquisas que dêem o suporte necessário para o desenvolvimento de competências (conhecimentos, habilidades e atitudes) para o farmacêutico e de ferramentas que facilitem a prática da automedicação responsável. Todavia, não há estudos, pelo que nos foi possível averiguar, no país, que tratem desta temática específica.

1.1 ESTRUTURA DA TESE

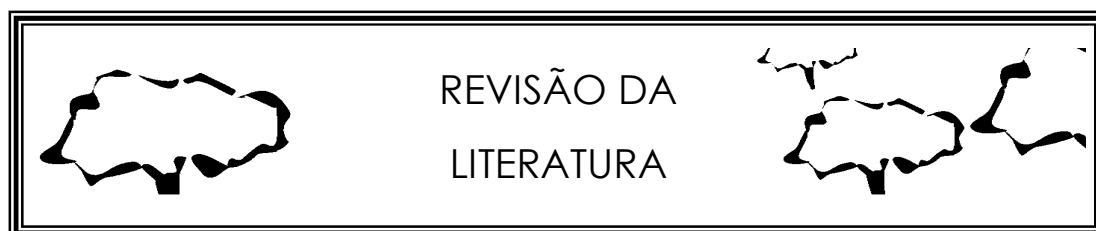
Esta tese foi estruturada em:

CAPÍTULO 1 - o capítulo 1 foi desenvolvido em formato de artigo intitulado como “Pharmacist interventions in managing minor illnesses with non-prescription medicines: a systematic review”, seguindo as normas do periódico científico *African Journal of Pharmacy and Pharmacology* ao qual foi submetido. Neste capítulo foi apresentada a qualidade dos estudos sobre intervenções farmacêuticas em sintomas menores com medicamentos não prescritos.

CAPÍTULO 2 - o capítulo 2 foi desenvolvido em formato de artigo intitulado “What do brazilian community pharmacists know about self-medication for minor illnesses? a pilot study in the northeast of Brazil”, seguindo as normas do periódico científico *Journal of Applied Pharmaceutical Science* o qual aceitou para publicação. Neste capítulo foram apresentados os resultados das entrevistas realizadas com farmacêuticos comunitários sobre a sua percepção quanto a definição de sintoma menor e sua atitude frente à prática da automedicação.

CAPÍTULO 3 - o capítulo 3, foi desenvolvido em formato de artigo sob o título “Assessment of the counselling practices of community pharmacists with simulated patients with minor illness – a pilot study”, seguindo as normas do periódico científico *Simulation in Healthcare* ao qual foi submetido. Neste capítulo foram apresentados os resultados do atendimento farmacêutico a dois pacientes submetidos a uma simulação que apresentavam sintomas menores e, para isto, nos baseamos no instrumento desenvolvido pela Farmacopéia dos Estados Unidos intitulado "Medication Counseling Behavior Guidelines" e validado para a língua portuguesa por Santos et al (2013).

CAPÍTULO 4 - o capítulo 4 foi desenvolvido em formato de artigo denominado “Sistema de suporte à tomada de decisão clínica do farmacêutico na provisão da automedicação responsável”, seguindo as normas do periódico científico *Simulation in Healthcare* o qual será submetido. Neste capítulo, foram apresentados os resultados do desenvolvimento do software contendo algoritmos de tomada de decisão clínica para o farmacêutico no manejo de sintomas menores do trato respiratório superior com medicamentos não prescritos.



2.1 A PRÁTICA DA AUTOMEDICAÇÃO

A automedicação é definida como o uso de medicamentos por parte dos indivíduos para tratar distúrbios e sintomas autodiagnosticados, ou o uso intermitente ou contínuo de um medicamento prescrito por um médico para doenças rônicas ou recorrentes ou sintomas menores (WHO, 2000; AWAD et al., 2005; FIP, 2013; WHO, 2013). Para tanto, esta prática envolve a aquisição de medicamentos sem receita médica ou via apresentação de prescrições pregressas, compartilhamento de medicamentos com parentes ou membros de seu círculo social ou o uso de sobras de medicamentos armazenados em casa (LOYOLA FILHO et al., 2004).

A automedicação com o uso de medicamentos não prescritos é a forma mais prevalente de autocuidado no mundo e, estima-se que cerca de 80% de todos os sintomas são resolvidos com o uso de medicamentos sem orientação de um profissional de saúde (ALBARRA et al., 2008; WERTHEIMER et al., 2008). Além disso, os sintomas menores constituem o principal motivo pelo qual o paciente procura a farmácia comunitária (WATSON et al., 2006). Na farmácia comunitária, os pacientes, ao solicitarem medicamentos sem a prescrição de um médico, descrevem a sua condição clínica ou fornecem, diretamente, o nome do produto desejado (GRIGORYAN et al., 2006; OLCZAK et al., 2006; PAGAN et al., 2006). A simplicidade no processo de aquisição destes medicamentos, atrelado ao seu baixo custo propiciam a autmedicação. Além disso, os meios de comunicação e a internet geram comportamentos arriscados na automedicação na medida em que pregam a falsa autonomia do paciente (KLEMENC-KETIS et al., 2011).

O aumento da publicidade dos medicamentos, apesar de propiciar acesso a informações via de regra tendenciosas, ao privilegiar os aspectos positivos do que se quer propagandar, sobre o autocuidado, não deixa de representar uma ameaça à população em geral, haja vista a reificação do medicamento como único meio de se manter ou obter saúde (LEFÈVRE, 1997; GÜL et al., 2007). O raciocínio do indivíduo que se automedica não considera diagnósticos errôneos – visto que são leigos em virtude do fato de não possuírem competência clínica – nem tão pouco informações a respeito de interações medicamentosas, seleção e uso de medicamentos ou que ultrapassem suas indicações originais (BURAK et al., 2000; YOU et al., 2011). Vale salientar que a publicidade intensiva sobre os medicamentos não prescritos, indicados para serem usados no alívio e tratamento rápido de sintomas menores, sem mencionar qualquer efeito indesejável advindo do seu uso, pode confundir os consumidores ou criar a falsa impressão de que determinado tipo de medicamento é necessário e essencial (BOND et al., 2003).

A automedicação é parte integrante das práticas de autocuidado (HEALTH GUIDANCE, 2013), e ela pode ser reconhecida como recurso da atenção primária à saúde (WHO, 2000). Estudos demonstram que a escolha pela automedicação se deve ao reconhecimento da queixa como simples e não grave pelo paciente, o longo tempo de espera pela consulta médica e o caráter agudo da queixa (KAYALVIZHI et al., 2010; GUPTA et al., 2011; KUMAR et al., 2013). Além disso, a percepção do paciente na crença de que a automedicação compõe as práticas de autocuidado ensejam atitudes de desejo em se automedicar e de manter esta prática (KUMAR et al., 2013). A automedicação com medicamentos não prescritos é comum em muitas culturas, notadamente, em países em desenvolvimento (NUNES DE MELO et al., 2006; SEDIGHI et al., 2006; KAGASHE et al., 2011; HUSSAIN et al., 2012; PHAM et al., 2013). Esta tendência é justificada devido à pouca oferta de serviços de atenção à saúde a que vem somar-se à ausência de médicos com compromisso e em ir para os rincões do país, aliado, ainda, ao grande contingente de destituídos de condições mínimas de vida. Assim, os indivíduos procuram, em primeiro lugar, a farmácia comunitária para auxiliá-los na resolução das suas queixas em saúde (AWAD et al., 2006; OLCZAK et al., 2006).

Contudo, é importante enfatizar que a automedicação sem a orientação de um profissional de saúde incrementa os riscos na utilização de medicamentos vencidos e de indicações terapêuticas equivocadas realizadas por parentes, amigos e vizinhos (LOYOLA FILHO et al., 2004). No cotidiano, o uso irracional de medicamentos culmina em reações indesejáveis e acidentais apesar de alguns pacientes reconhecerem a ocorrência de interações medicamentosas, a necessidade de atendimento clínico especializado e o risco de compartilhar medicamentos para sintomas semelhantes com terceiros (YOU et al., 2011; KUMAR et al., 2013).

Importante destacar é que a automedicação apresenta vantagens e desvantagens, a depender de quem a pratica (indivíduos leigos com baixo ou alto grau de escolaridade ou profissionais de saúde) e de como e qual o medicamento é escolhido (HEALTH GUIDANCE, 2013). Em consequência, as instituições de saúde e seus profissionais têm despendido diversos esforços a fim de aumentar a responsabilidade dos indivíduos pela sua condição de saúde, por meio do estímulo às práticas de autocuidado para prevenção de doenças e manutenção da saúde (WHO, 2013).

Quando praticada corretamente, as principais vantagens da automedicação são o alívio dos sintomas e a redução da demanda dos sistemas de saúde (ALBARRA et al., 2008). Desta forma, a OMS (1995) assinala que a automedicação responsável pode ser útil na prevenção e

no tratamento de doenças que não requerem consulta médica, sendo uma alternativa menos onerosa para o tratamento de doenças comuns.

Quanto às desvantagens, a morbimortalidade relacionada aos medicamentos é um dos problemas mais graves da automedicação (PORTEOUS et al., 2006; FREI et al., 2010; COOPER, 2013). Na prática, a escolha autônoma de determinados medicamentos pelo paciente pode mascarar sinais e sintomas, gerando prejuízos à saúde (COOPER, 2013) e altos custos dos sistemas de atenção sanitária (PORTEOUS et al., 2006; FREI et al., 2010). Apesar disso, o uso de medicamentos não prescritos é aceito como parte integrante do sistema de saúde (OMS, 1998). Estes medicamentos podem ser adquiridos pelo paciente sem a apresentação de uma prescrição médica (ANVISA, 2003). Todavia, a sua utilização é preocupação social constante, devido ao fácil acesso da população que, em muitas ocasiões, os adquire sem que ocorra contato com o profissional de saúde no manejo da condição clínica e na indicação do medicamento (BISSEL et al., 2001; CHANG et al., 2003; MELO et al., 2007; TYTGAT et al., 2008).

Diante dessas vantagens e desvantagens, os pacientes precisam distinguir os limites destas práticas e reconhecer quando a intervenção de um profissional de saúde, como o farmacêutico, é necessária (SPROTT et al., 2006). Importante destacar que farmacêutico comunitário é o profissional de saúde mais acessível para prestar cuidados em saúde, inclusive no autocuidado e na automedicação (OMS, 1993; GÜL et al., 2007).

2.2 PAPEL DO FARMACÊUTICO NA AUTOMEDICAÇÃO

No final da década de 1990, Nimmo e Holland (1999) diferenciaram os tipos de serviços prestados pelo farmacêutico na farmácia comunitária. No modelo de distribuição de medicamentos, o foco do farmacêutico é fazer o medicamento correto chegar no tempo certo para o paciente adequado, provendo apenas orientações básicas sobre sua utilização. Por outro lado, o modelo de dispensação farmacêutica foca na provisão de informações mais aprofundadas sobre medicamentos e educação em saúde para mudança do estilo de vida e prevenção de doenças passando a constituir um serviço cognitivo e não mais, apenas, um serviço técnico (NIMMO et al., 1999). Nesse contexto, o farmacêutico é um promotor da saúde e deve prover informações ao usuário a fim de que o mesmo escolha o melhor produto para prevenir e tratar doenças (OMS, 1995; HASSELL et al., 2001; YOU et al., 2011).

Desde a década de 1960, nos Estados Unidos, iniciou-se a mudança de paradigma da profissão farmacêutica no sentido de adotar atividades clínicas em sua rotina de atividades.

Em consequência, o farmacêutico passou a ser visto como um prestador de serviços cognitivos (dispensação, orientação, promoção e educação em saúde, administração de medicamentos e de vacinas, detecção e acompanhamento de doenças crônicas, acompanhamento do uso de medicamentos para tratamento da AIDS, programas de cessação do tabagismo e acompanhamento domiciliar) que atua em contato direto com os pacientes, no atendimento das suas necessidades clínicas, humanísticas e econômicas (SILVESTRE et al., 2012).

Diante disso, pode-se afirmar que os serviços cognitivos são aqueles voltados ao paciente que exigem conhecimento específico do farmacêutico com o objetivo de melhorar tanto o processo de uso dos medicamentos quanto os resultados da farmacoterapia (GASTELURRUTIA et al., 2009). A prestação destes serviços é comum nos Estados Unidos, Bélgica, Itália, Holanda, Portugal, Austrália, Gana, Bangladesh e o Paquistão (BENRIMOJ et al., 2004; AZHAR et al., 2009; MANOLAKIS et al., 2010; CHISHOLM-BURNS et al., 2010; ADDO-ATUAH, 2011; ANF, 2011).

Por outro lado, a maioria dos países da América do Sul ainda adota o modelo distributivo de medicamentos. No Brasil, este modelo propiciou, de certa maneira, que os farmacêuticos priorizassem a realização de atividades de gestão em detrimento à prestação dos serviços técnico-assistenciais. Todavia, na Argentina e no Chile, a farmácia é considerada um posto avançado de saúde e, algumas redes e farmácias independentes, fazem propaganda da qualidade e da credibilidade dos seus farmacêuticos comunitários (PAULÓS et al., 2005; ARMANDO et al., 2007; UEMA et al., 2008).

De modo geral, a procura pela orientação do farmacêutico comunitário ocorre pela existência de dúvidas quanto à escolha do medicamento não prescrito apropriado para determinada condição clínica (PIECUCH et al., 2013). Cabe ao farmacêutico constatar sinais e sintomas de doenças autolimitadas e a tomada de decisão, na escolha do medicamento não prescrito ou no encaminhamento do usuário para outro membro da equipe, principalmente, quando forem identificadas situações de risco à saúde (YOU et al., 2011). Além disso, os farmacêuticos comunitários devem dispensar o medicamento solicitado, ofertando informações confiáveis sobre cuidados à saúde e à farmacoterapia, requerendo mais tempo para interagir com o paciente (CAAMAÑO-ISORNA et al., 2005; WERTHEIMER et al., 2008; AL-ARIFI, 2012).

Ante ao exposto, o farmacêutico está em posição ímpar para indicar produtos e orientar os pacientes sobre atividades de autocuidado apropriadas (NCPIE, 2003a; NCPIE, 2003b; COVINGTON, 2006). Estudos demonstram que alguns comportamentos adotados pelos

pacientes no processo de tratamento de doenças e de utilização do medicamento aumentam os riscos à saúde (SHELLEY et al., 2009; YOU et al., 2011; RUIZ, 2010; PAN et al., 2012). Assim como acontece nas demais profissões de saúde, a interação farmacêutico-paciente, com o objetivo de melhorar o processo de cuidado, permite estabelecer vínculos e obter informações clínicas e farmacoterapêuticas do paciente, proporcionando a identificação de situações de risco à saúde advindas das práticas do autocuidado e automedicação (AL-ARIFI, 2012). A partir deste papel alguns países já reconhecem as vantagens advindas da prescrição farmacêutica.

A prescrição farmacêutica está regulamentada em nível nacional no Reino Unido (DEPARTMENT OF HEALTH, 2006) e no Canadá (LAW et al., 2012). Nestes países, o farmacêutico habilitado e licenciado pode prescrever medicamento de forma dependente ou independente, tanto para condições diagnosticadas como não diagnosticadas, solicitar exames laboratoriais, realizar exame físico e manejar a farmacoterapia de condições de saúde agudas ou crônicas (EMMERTON et al., 2005; TONNA, 2007).

No Brasil, o ato da prescrição farmacêutica está prevista na legislação vigente para plantas medicinais e fitoterápicos de venda livre, bem como medicamentos manipulados (BRASIL, 2008; BRASIL, 2011). Mais recentemente, as atribuições clínicas do farmacêutico foram regulamentadas com a Resolução do Conselho Federal de Farmácia nº 585, de 29 de agosto de 2013, que aponta a prescrição farmacêutica como um dos fins da prestação de cuidados farmacêuticos (BRASIL, 2013a). Esta resolução destaca, entre outras atribuições clínicas do farmacêutico, a realização e o registro das intervenções farmacêuticas junto ao paciente, família, cuidadores e sociedade, dá suporte ao paciente, aos cuidadores, à família e à comunidade com vistas ao processo de autocuidado, incluindo o manejo de problemas de saúde autolimitados e prescrever, conforme legislação específica, no âmbito de sua competência profissional (BRASIL, 2013a).

A prescrição farmacêutica, no Brasil, foi também, recentemente, regulamentada pela Resolução do Conselho Federal de Farmácia nº 586, de 29 de agosto de 2013. A referida resolução determina em quais situações, lugares e condições deverão ocorrer a prescrição farmacêutica. Entre estas, o ato da prescrição se aplica aos medicamentos cuja dispensação não exija a prescrição médica, adquiridos via automedicação (BRASIL, 2013b). Logo, a aprovação destas resoluções atende a evolução e a capilarização do cuidado em saúde antes e, exclusivamente, no cerne da prática médica.

Em todo o mundo, as demais profissões de saúde também ofertam assistência especializada ao paciente e proporciona o alívio da pressão por cuidados médicos (HASSELL

et al., 1999; YOUSEF et al., 2009; WERTHEIMER et al., 2008). Tal assertiva não é diferente à prática farmacêutica quando se trata do cuidado com os medicamentos (AL-ARIFI, 2012). No entanto, a falta de formação específica (comunicação interpessoal, semiologia farmacêutica, farmacoterapia, etc.) e instrumentos (algoritmos, protocolos, etc.) que otimizem a atuação do farmacêutico comunitário obstaculizam a concretização desta atribuição clínica (BUCKLEY et al., 2006; MESQUITA et al., 2013).

A utilização de algoritmos e protocolos é interpretada, de forma positiva, no tocante ao manejo de doenças autolimitadas pelo farmacêutico comunitário e pelos médicos (SMITH, 1996; ARADOTTIR et al., 2008). Para tanto, os farmacêuticos comunitários devem acompanhar os algoritmos, a fim de realizar a avaliação do paciente, julgar a necessidade do encaminhamento, realizar investigações não invasivas e estabelecer os tratamentos (ARADOTTIR et al., 2008). Somado a isso, os algoritmos darão o suporte necessário para que os pacientes sejam encaminhados ao médico caso o tratamento com o medicamento não prescrito falhe ou se as condições clínicas do paciente forem graves (ARADOTTIR et al., 2008). Portanto, é viável o desenvolvimento de instrumentos que auxiliem o processo de avaliação e decisão farmacêutica.

Os protocolos e algoritmos proporcionam serviços farmacêuticos baseados em evidência e, conseqüentemente, melhoram a gestão da automedicação responsável. Além disso, otimizam a atividade do médico que terá maior tempo com os pacientes cujos quadros clínicos sejam mais complexos (BOND et al., 2003; ARADOTTIR et al., 2008). Assim, o farmacêutico comunitário acessa formas de manejo com base em perguntas e resposta para guiar suas orientações. Adicionalmente, o algoritmo serve de base para replicar as recomendações presentes nos protocolos.

2.3 A IMPORTÂNCIA DOS ALGORITMOS E PROTOCOLOS DE DECISÃO NA PRÁTICA DO FARMACÊUTICO COMUNITÁRIO

Vários estudos apontam que o tratamento de sintomas menores pode ser realizado de forma satisfatória nas farmácias comunitárias com o uso de medicamentos não prescritos (BOJKEA et al., 2004; MEHUYS et al., 2009). Porém, a escolha da melhor farmacoterapia requer suporte do farmacêutico (WHO, 1993). A este profissional também cabe a responsabilidade de identificar sinais e sintomas menores de agravos à saúde e a tomada de decisão, no que diz respeito ao encaminhamento do paciente para outro membro da equipe, principalmente, quando forem identificadas situações de risco à saúde (WERTHEIMER,

2008; PORTEOUS et al., 2006; WAZAIFY et al., 2008; TYTGAT et al., 2008). Para tanto, o mesmo deve estar munido de instrumento de suporte à prática clínica como protocolos e algoritmos.

Os protocolos de tratamento constituem um plano que especifica os procedimentos a serem seguidos na realização de determinado exame, pesquisas ou prestação de cuidados a uma condição particular (MOSBY'S, 2009). Por sua vez, os algoritmos de tratamento são desenvolvidos para proporcionar aos profissionais de saúde uma referência rápida à tomada de decisão no manejo de uma condição clínica presente nos protocolos (McGHAN, 1996). Segundo Campolina (2006), o algoritmo deve ser complexo o suficiente para incorporar todos os elementos chaves e valores que são importantes e, ao mesmo tempo, simples o suficiente para ser compreensível e operacional.

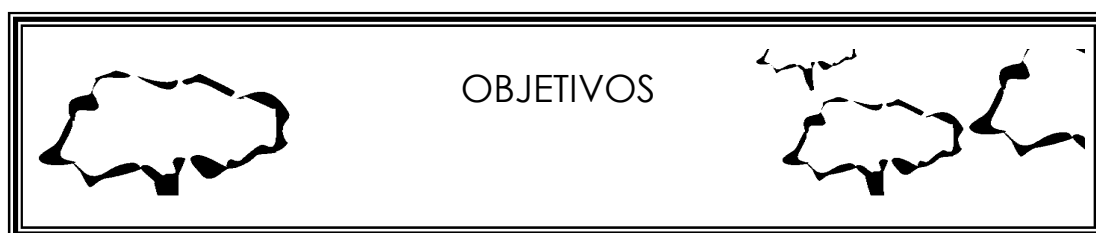
Atualmente, os protocolos clínicos disponíveis oferecem suporte à prática médica e, portanto, são escassos os voltados para o manejo, com medicamentos não prescritos, de sintomas que são apresentados pelos pacientes ao farmacêutico comunitário (MATHESON et al, 1998; ARADOTTIR, 2008). Para a sua tomada de decisão quanto à dispensação do medicamento não prescrito indicado, efetivo, seguro e conveniente, o farmacêutico tem a sua disposição apenas as informações relatadas e extraídas do paciente sobre a condição clínica (HASSELL et al, 2001). De acordo com Holtmann (2011), o desenvolvimento de algoritmos de tomada de decisão proporciona melhor suporte ao farmacêutico quanto à avaliação do sintoma menor apresentado pelo paciente, por exemplo, azia e cefaléia e a indicação adequada do medicamento não prescrito (HANNA et al 2010) .

No Brasil, o Conselho Federal de Farmácia, ao aprovar as resoluções 357/2001, a 499/2008, a RDC 44/2009 e a resolução 586/2013 contemplaram os avanços da prática profissional, no que diz respeito à automedicação responsável. Da mesma forma, a Resolução da Diretoria Colegiada 138/2003 da Anvisa trata dos medicamentos não prescritos destinados ao tratamento de sintomas menores, sugerindo que o farmacêutico poderá participar auxiliando a automedicação. A aprovação da Resolução 586/2013 (BRASIL, 2013) possibilitou que esta prática se torne uma realidade no país. No entanto, é importante mencionar a necessidade de instrumentos adequados, como protocolos e algoritmos de tomada de decisão para auxiliar na prestação deste serviço farmacêutico, como destacado no artigo 6º e no parágrafo 1º do mesmo artigo da Resolução 586/2013 (BRASIL, 2013).

Em 2009, de acordo com o Sistema Nacional de Informações Tóxico-Farmacológicas (SINITOX), 2,75% dos casos de intoxicação registrados foram causados por automedicação. As pessoas que sofrem intoxicação por medicamentos, seja acidental ou proposital, de certa

forma, tornam-se permanentemente dependentes dos serviços de saúde, exigindo estrutura médico-hospitalar efetiva e aumentando os custos do setor. Portanto, todas as iniciativas que visem reduzir o impacto deste panorama na saúde pública são válidas.

Com base nesses dados, a introdução de novas práticas no âmbito farmacêutico são fundamentais para a otimização do uso de medicamentos. Neste sentido, o desenvolvimento de práticas como manejo de sintomas menores, utilizando algoritmos de decisão, pode fundamentar a aprendizagem dos farmacêuticos, pois os instrumentalizará para atender as demandas sociais a partir das necessidades do paciente.



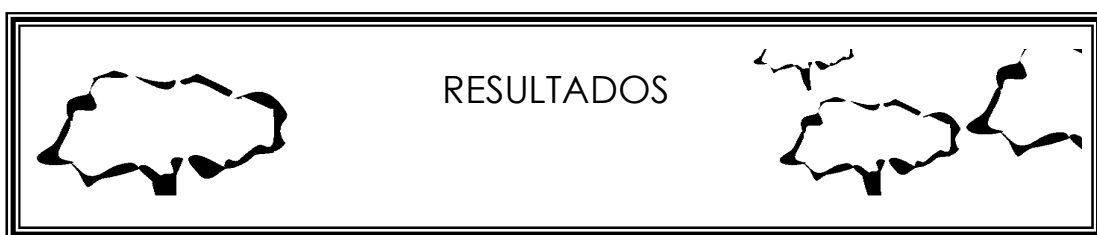
3. OBJETIVOS

3.1. Objetivo geral

Desenvolver software de suporte à decisão clínica para intervenções farmacêuticas na prática da automedicação responsável.

3.2. Objetivos específicos

- Realizar revisão sistemática da literatura sobre as intervenções farmacêuticas no manejo de sintomas menores com medicamentos não prescritos.
- Descrever o conhecimento dos farmacêuticos comunitários sobre o manejo de sintomas menores com medicamentos isentos de prescrição na prática da automedicação.
- Analisar o desempenho de farmacêuticos comunitários no manejo de sintomas menores.
- Elaborar algoritmos para o manejo de sintomas menores com medicamentos não prescritos a serem incorporados em um software de decisão clínica.



4.1 CAPÍTULO I - PHARMACIST INTERVENTIONS IN MANAGING MINOR ILLNESSES WITH NON-PRESCRIPTION MEDICINES: A SYSTEMATIC REVIEW

PHARMACIST INTERVENTIONS IN MANAGING MINOR ILLNESSES WITH NON-PRESCRIPTION
MEDICINES: A SYSTEMATIC REVIEW

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ABSTRACT

OBJECTIVES: Evaluate the outcomes of pharmacist interventions in managing minor illnesses with non-prescription medicines. **METHOD:** The Embase, LILACS, PubMed, Scielo, EBSCO, and Scopus databases were searched for articles published from 1980 through December 2010 with the search terms “minor ailments,” “minor illness,” “pharmacist,” “self-medication,” “pharmacist's role,” “self limiting conditions,” “community pharmacies,” “over-the-counter,” “pharmacy information,” and “non-prescription drug.” The inclusion criteria were research conducted in community pharmacies, consumers of non-prescription medicines for the management of minor illness, pharmacist intervention for management of minor illness with non-prescription medicines, and presence of questions that indicate management of minor illness. **RESULTS:** The initial search identified 1,290 publications. Of these, only 9 met our inclusion criteria. None of the articles defined minor illness and non-prescription drugs. Only 4 (44.4%) made any reference to pharmacist intervention. The most common pharmacist intervention was non-prescription drugs. **CONCLUSION:** Most of the studies evaluated pharmacist actions in providing appropriate care to consumers seeking non-prescription treatment for minor illness, the level of patient adherence, and the impact of pharmacist counseling on the patient's complaint. However, this research revealed that pharmacist interventions were scarce and even the articles that deal with this verified a lack of practical measures that indicate their impact.

Key words: pharmacist's intervention; non-prescription medicines; community pharmacist; minor illness.

INTRODUCTION

A study established that 80% of medical symptoms were self-recognized and self-treated without healthcare professionals involvement (Sobel, 2003). According to Shoemaker et al. (2008) this behavior, called self-care, results from natural survival instinct. Levin et al. (1997) defined self-care as “a decision-making process which involves self-observation, symptom perception and labeling, judgment of severity, and choice and assessment of treatment options.”

Self-medication is a necessary part of healthcare systems; it is a form of self-care in which patients assess the severity of illness and the outcomes expected from non-prescription medicines treatment (Volmer et al., 2007). Worldwide, the management of minor illness by self-medication is a common practice, as patients are taking more interest and feel more confident in managing their own

health and drug therapy (Parmentier et al., 2004; Wazaify et al., 2005; Schulz et al., 2006; Grigoryan et al., 2006; Chin-Quee et al., 2006; Noyce, 2007; Puntong et al., 2008; Hanna et al., 2009).

Although the advent of medication use is one of the most significant contributions to increased life expectancy, medication-related problems, ie, negative clinical outcomes resulting from the medication use (or lack of use), are a greater contributor to burden of disease (Llimós et al., 2003). An example of negative clinical outcomes is the acetaminophen, recognized as a safe and effective non-prescription analgesic and antipyretic, it is also associated with significant morbidity and mortality (hepatotoxicity) when doses in excess of the therapeutic amount are ingested inappropriately (Krenzelok et al., 2012). An estimated 78,414 emergency department visits for the treatment of acetaminophen overdose occur annually in the United States (Budnitz et al., 2011). According Major et al. (2010), the risks associated with non-prescription medicines could be particularly great because consumers do not normally follow up with their pharmacist.

In consequence, the World Health Organization (1998) proposed guidelines for healthcare professionals, including pharmacists, specifically intended to minimize the risk of inappropriate medication use, primarily non-prescription medicines (WHO, 1998; Ernst et al., 2001). In recent decades, the literature has reported that pharmacists have clinical skills and have made pharmacotherapy interventions to help patients choose adequate non-prescription medicines (NPA, 1989; Van Duong et al., 1997; Ernst et al., 2001; Philips et al., 2001; Sobel, 2003; Marklund et al., 2003; Westerlund et al., 2003; Wazaify et al., 2005; Chin-Quee et al., 2006; Qidwai et al., 2006; Noyce, 2007; Westerlund et al., 2007; Smith, 2009; Vella et al., 2009; Major et al., 2010; Holtmann et al., 2011; Kagashe et al., 2011; Hussain et al., 2012; Minh et al., 2013). The present study aimed to evaluate the outcomes of pharmacist interventions in managing minor illnesses with non-prescription medicines.

MATERIAL AND METHOD

A systematic review was conducted according to Cochrane methodology (Higgins et al., 2006). Six databases were searched: Embase, LILACS, PubMed, Scielo, EBSCO, and Scopus. Articles published from January 1980 through December 2010 were searched using different combinations of the following terms: "minor ailments", "minor illness", "pharmacist", "self-medication", "pharmacist's role", "self limiting conditions", "community pharmacies", "over-the-counter medication",

“pharmacy information”, and “non-prescription drug”. Articles indexed in multiple databases were considered only once.

The inclusion criteria were as follows: (1) research conducted in community pharmacies, (2) consumers of non-prescription medicines for the management of minor illness, (3) pharmacist intervention for management of minor illness with non-prescription medicines, and (4) the presence of questions that indicated management of minor illness and/or decision making about the supply of non-prescription medicines. Letters to the editor, congress publications, systematic reviews, meta-analyses, articles not written in English, articles without abstracts or full text available in the databases or by the article authors, patient preferences for non-prescription medicines and attitude about minor illness, articles focusing exclusively on medicine, and only provision of medicines (without counseling) were excluded from this review. Studies evaluating pharmacist intervention and presenting results obtained by pharmacy staff without specifying the results of pharmacist intervention (data stratification or other statistical method) were also excluded.

The selection process comprised 3 phases. The manual screening of titles (phase 1) and then abstracts (phase 2) was performed by two independent reviewers (M.L.B. and C.E.R.). The selected articles were then manually reviewed (phase 3) by the same reviewers of phase 1 and 2, and included or excluded on the basis of the previously mentioned criteria. Any disagreement during phases 2 and 3 were resolved at a meeting where abstracts and articles were analyzed regarding the presence of the inclusion criteria and, subsequently, included or excluded from the systematic review (M.L.B., C.E.R., and D.P.L.J.). The rate of agreement between the two reviewers before and after consensus was assessed by the kappa coefficients (κ). If the reviewers could not reach a consensus, a third independent reviewer (D.P.L.J.) resolved the disagreement.

The reviewers independently abstracted critical information from selected articles, including (1) study setting; (2) sample size (community pharmacy), participant, and participant age; (3) reference to minor illness; (4) reference to pharmacist intervention; (5) reference to non-prescription medicine; (6) study design; (7) duration of the study and pharmacists' consultations; (8) minor illness managed; (9) non-prescription medicines used; (10) most common questions pharmacists asked; (11) type of pharmacist intervention; (12) criteria for pharmacists' decision to recommend a non-prescription medicines; (13) reasons for referring a consumer to a medical practice or other services; (14) patient

adherence to the pharmacist's advice; (15) outcomes after pharmacist intervention; and (16) study limitations.

In this study, pharmacist intervention outcomes was identified through the attitudes of pharmacists involving the evaluation of patient complaints and indication of a pharmacological or non-pharmacological treatment that would modified the patient clinical condition (stabilization, improvement or worsening of the complaint). Minor illness was considered, according Gray et al. (2002) a self-limiting condition, e.g., a cold, which does not require referral to a clinician or other health professional. Non- prescription medicines was defined, in this study, as drugs that do not need a doctor's prescription, and are used in minor illness treatment or self-limiting conditions (Wertheimer et al., 2008). Finally, patient adherence to pharmacist's advice was identified as patient spontaneous acceptance of pharmacist recommendations that included, for example, non-pharmacological treatment, medical consultation, and concordance with pharmacotherapy.

The Preferred Reporting Items of Systematic reviews and Meta-Analyses PRISMA statement was used to make a flow chart of the selection process (Moher et al., 2009).

RESULTS

Figure 1 summarizes the systematic review strategy.

The kappa calculated in phase 2, after consensus, indicates substantial agreement ($\kappa = 0.79$; $p < 0.001$) between our 2 reviewers (Fig. 1). A total of 95 articles were pre-selected for full-text review, and 86 of these were excluded: 12 because the full text, after exhaustive search, was not available in the databases or because they were not provided by the article authors and 74 because they did not meet the inclusion criteria.

Perfect agreement ($\kappa = 1.00$; $p < 0.001$) between our 2 reviewers was found in phase 3, after consensus (Fig. 1). Nine articles comprised the final data set (Berih et al., 1989; Krishnan et al., 2000; Westerlund et al., 2003; Rutter et al., 2004; Chui et al., 2005; Alte et al., 2007; Driesen et al., 2009; Mehuys et al., 2009; Saengcharoen et al., 2010). Table 1 describes the characteristics of these selected studies in detail.

Almost all of the studies analyzed (8/9; 88.9%) were published in pharmacy journals (Krishnan et al., 2000; Westerlund et al., 2003; Rutter et al., 2004; Chui et al., 2005; Alte et al., 2007; Driesen et al., 2009; Mehuys et al., 2009; Saengcharoen et al., 2010). The studies were conducted primarily in Europe (6/9; 66.7%) (Krishnan et al., 2000; Westerlund et al., 2003; Rutter et al., 2004; Alte et al.,

2007; Driesen et al., 2009; Mehuys et al., 2009) and Asia (2/9; 22.2%) (Chui et al., 2005; Saengcharoen et al., 2010). Participants in 4 (44.4%) studies were simulated patients and pharmacist (Berih et al., 1989; Rutter et al., 2004; Alte et al., 2007; Driesen et al., 2009) in the practice setting. The simulated patient age was reported in 2 studies, and the age ranged from 26 to 55 (Berih et al., 1989; Driesen et al., 2009). Concerning to community pharmacies sample size, the reviewed studies presented the ranged from 6 (Westerlund et al., 2003) to 146 (Alte et al., 2007), and more than half of the studies (6/9; 66.7%) had community pharmacies samples smaller than 100 (Westerlund et al., 2003; Berih et al., 1989; Krishnan et al., 2000; Rutter et al., 2004; Chui et al., 2005; Saengcharoen et al., 2010). Only 5 (55.5%) of the articles reviewed included a sample size calculation (Alte et al., 2007; Saengcharoen et al., 2010) or presented the sampling method (Westerlund et al., 2003; Rutter et al., 2004; Driesen et al., 2009). The length of study period duration was shorter than 3 months (6/9; 66.7%) (Westerlund et al., 2003; Berih et al., 1989; Rutter et al., 2004; Chui et al., 2005; Alte et al., 2007; Driesen et al., 2009) or greater than or equal to 6 months (Krishnan et al., 2000; Mehuys et al., 2009), and 1 study did not report this information (Saengcharoen et al., 2010). The amount of time the pharmacist spent dispensing medicines was reported in only 2 articles (1.5 min and 19 min) (Chui et al., 2005; Driesen et al., 2009).

None of the articles in the sample pointed out what would be considered as minor illness and non- prescription medicine (Berih et al., 1989; Krishnan et al., 2000; Westerlund et al., 2003; Rutter et al., 2004; Chui et al., 2005; Alte et al., 2007; Driesen et al., 2009; Mehuys et al., 2009; Saengcharoen et al., 2010) (Table 2). Only 4 (44.4%) made any reference of what would be considered as pharmacist intervention (Krishnan et al., 2000; Alte et al., 2007; Driesen et al., 2009; Mehuys et al., 2009). The most common minor illness managed was gastrointestinal symptoms (8) (Berih et al., 1989; Westerlund et al., 2003; Krishnan et al., 2000; Rutter et al., 2004; Driesen et al., 2009; Mehuys et al., 2009; Saengcharoen et al., 2010); and 5 of those were upper gastrointestinal symptoms (Krishnan et al., 2000; Westerlund et al., 2003; Rutter et al., 2004; Chui et al., 2005; Mehuys et al., 2009). Three studies described antacids as the non- prescription medicine recommended by the pharmacist (Westerlund et al., 2003; Rutter et al., 2004; Mehuys et al., 2009). It was also noted that of the 9 studies analyzed, only 4 (44.4%) (Krishnan et al., 2000; Westerlund et al., 2003; Chui et al., 2005; Mehuys et al., 2009) reported patient adherence to the pharmacist's advice.

The type of study was shown in 6 (66.7%) of our sample (Krishnan et al., 2000; Rutter et al., 2004; Chui et al., 2005; Driesen et al., 2009; Mehuys et al., 2009; Saengcharoen et al., 2010), and of those 1 (16.6%) used qualitative methods (Rutter et al., 2004) (Table 3). Eight studies thoroughly documented the questions community pharmacists asked to patients with minor illness (Krishnan et al., 2000; Westerlund et al., 2003; Rutter et al., 2004; Chui et al., 2005; Alte et al., 2007; Driesen et al., 2009; Mehuys et al., 2009; Saengcharoen et al., 2010); 6 indicated the reasons for referring patients to a medical practice or other services (for example, contraindications to self-treatment, serious illness, or current medication use), (Table 3) (Krishnan et al., 2000; Westerlund et al., 2003; Rutter et al., 2004; Alte et al., 2007; Driesen et al., 2009; Mehuys et al., 2009; Saengcharoen et al., 2010). Regarding criteria for recommending non-prescription medicine, pharmacists in 5 studies assessed previous use of these medicines (Westerlund et al., 2003; Alte et al., 2007) or minor illness symptoms (Chui et al., 2005; Driesen et al., 2009; Mehuys et al., 2009). In this review, 10 different types of pharmacist intervention were identified, and there was more than 1 intervention in each study (Table 4) (Berih et al., 1989; Krishnan et al., 2000; Westerlund et al., 2003; Rutter et al., 2004; Chui et al., 2005; Alte et al., 2007; Driesen et al., 2009; Mehuys et al., 2009; Saengcharoen et al., 2010). Positive outcomes included patient satisfaction (3) (Westerlund et al., 2003; Krishnan et al., 2000; Chui et al., 2005). The most often limitations cited for the articles reviewed were non-respondent bias and/or the reason (2) (Rutter et al., 2004; Mehuys et al., 2009), and lack of measurement of inter and intra-observer variation (2) (Rutter et al., 2004; Alte et al., 2007) (Table 3).

DISCUSSION

In practice, patients often go directly to community pharmacies and obtain medicines for their minor illness. Consequently, researchers need to recognize tools for implementing new counseling practices for the development of community pharmacist competency, as well, as ensure that the medication supplied was indicated, effective and safe for the patient clinical condition (Basak et al., 2010). Many of the suggestions for future research thus far lead us to explore the clinical and consultation skills pharmacists require, for example, diagnosis and treatment of self-limiting conditions knowledge, clinical pharmacy and therapeutics education, participation in clinical practice, structuring of clinical decision-making, and communication skills (WHO, 2012). Innovations in pharmacy practice tend to be reported in specialist journals, however, interdisciplinary collaboration among researchers and community pharmacists is essential.

Most of the studies we reviewed were conducted in Europe; we found no research from North America that met the inclusion criteria. The role of the pharmacist in the treatment of minor illness with non- prescription medicines in the US is different from the practice model in Europe (CHPA, 2012; CHPA, 2013; Nissen, 2011). It should be noted that pharmacy associations in the US also campaign for continuing education of community pharmacists and for pharmacists supplying of non- prescription medicines. To note one example, the American Pharmacist Association (APhA) offers a multi-module training program for pharmacists on advising patient's about over-the-counter products called Over the Counter (OTC) Advisor® and has also campaigned for a new drug class called "Pharmacist Care OTC" that would require patients to interact with a pharmacist to obtain certain OTC medications (APha, 2013). Future studies should focus on collecting information about community pharmacy practice, such as evidence-based self-care advice, and investigating effective follow-up methods.

Few studies presented a sample size calculation (Alte et al., 2007; Saengcharoen et al., 2010) or the sampling method (Westerlund et al., 2003; Rutter et al., 2004; Driesen et al., 2009), and there was variation in sample size (Berih et al., 1989; Krishnan et al., 2000; Westerlund et al., 2003; Rutter et al., 2004; Chui et al., 2005; Alte et al., 2007; Driesen et al., 2009; Saengcharoen et al., 2010). The absence of sample size calculations prevent us from detecting important effects of pharmacist interventions (Krishnan et al., 2000; Driesen et al., 2009), and compromise the statistical power of the study and the validity of the results (Chadha, 2006). Participants had different roles (pharmacist, simulated patients, and patients) with broad age ranges (Berih et al., 1989; Westerlund et al., 2003; Rutter et al., 2004; Chui et al., 2005; Alte et al., 2007; Driesen et al., 2009; Mehuys et al., 2009; Saengcharoen et al., 2010). Participant age should be included in future studies, whether patients or simulated patients are involved, because different minor illness affect distinct age groups. For example, younger patients typically needed information of their acute and minor illness, and elderly patients needed information more about chronic major diseases such as cardiovascular or respiratory (Kansanaho et al., 2002).

The effectiveness of pharmacist intervention was not related to the length of study period duration, but to characteristics of the design and expected outcomes. Some studies focused on follow-up and measured the impact of pharmacist intervention (Krishnan et al., 2000; Westerlund et al., 2003; Mehuys et al., 2009). Nevertheless, the advice given about medicine had a positive outcome (for example, relief of patient dyspepsia symptoms, patient satisfaction with the visit to the pharmacy or

with pharmacists' consultation, patient adherence to the pharmacist's referral advice); usually, 1 encounter was not enough to demonstrate the full scope of pharmacist counseling (Aguilar et al., 2011). Researchers should develop more studies with two or more pharmacist encounter to understand and measure the improvement on patient health, for example relief of patient complaint. These studies should use artifices like future discounts on medicines purchase or telephone contact with the patient in order to inform the pharmacist about the effect of the proposed intervention.

To recommend properly a non- prescription medicine for a patient, pharmacist requires adequate time for gathering clinically relevant information and evaluating the need for the medicine. The literature advocates that pharmacists designate at least 3 minutes per patient (Oh et al., 2002). Future researchers should consider not only the duration of pharmacist-patient interaction, but also the quality and scope of information exchange and patients' understanding of this information. Investigators who are experienced in qualitative research can fill these crucial gaps in our understanding of pharmacist intervention.

Although the scope of self-medication is increasing, which encourages patients to seek out community pharmacies, worldwide understanding of minor illness is not uniform. When a study does not clearly define minor illness, this may lead to different interpretations of the results; the impact of pharmacist intervention may not be measured. It is important that researchers standardize the definition of minor illness, because this would facilitate the exchange of pharmacist intervention data and influence continuing education.

Likewise, few studies defined pharmacist intervention. The literature defines "intervention" as any activity that changes a patient's treatment (Cordina et al., 1998). Researchers need to understand what kind of activities would be investigated to assess the real impact of pharmacist intervention at a community pharmacy. Again, documentation (including audio and video recordings) could be a relevant indicator of the quality and extent of pharmacist intervention.

Although a number of studies specified the non-prescription medicines supplied, none of them defined the term non-prescription medicines. Non-prescription medicines are medications bought by patients without a physician's prescription. Studies have shown that self-care might empower patients to become responsible users of medications obtained after suitable counseling and education (Shoemaker et al., 2008). Examining patient experience with the minor illness and non-prescription medicines will help future investigators in planning management strategies; understanding the effect of

new information on patient experience; and understanding how partnerships influence the patient's adherence to the pharmacist's advice (Shoemaker et al., 2008).

Some articles did not report the study design (Berih et al., 1989; Westerlund et al., 2003; Alte et al., 2007), and several studies reported quantitative (Krishnan et al., 2000; Chui et al., 2005; Driesen et al., 2009; Mehuys et al., 2009; Saengcharoen et al., 2010) and qualitative (Rutter et al., 2004) methods. The selection of one design over another depends on the research question, concerns about validity and efficiency, practical and ethical considerations, and expected outcomes (Aschengrau et al., 2008). Future study designs must address how problems will be described and quantified, and whether associations between variables will be assessed. Qualitative techniques, such as focal group, in-depth interviews, and participant observation, could help future researchers comprehend patients' perception/understanding/interpretation of the minor illness, and their experience managing medication (Shah et al., 2006; Aschengrau et al., 2008). Similarly, methods like simulated patients or the theory of planned behavior might also be used in these investigations, depending upon the type of study being performed (Berih et al., 1989; Rutter et al., 2004; Alte et al., 2007; Driesen et al., 2009; Saengcharoen et al., 2010).

As noted in this review, only Berih et al. (1989) did not use questions to gather evidence and explain the minor illness presented. Other studies showed that tools like mnemonic questions, clinical protocols, algorithms, and software can also facilitate responsible self-medication (Krishnan et al., 2000; Westerlund et al., 2003; Driesen et al., 2009; Mehuys et al., 2009). Watson et al. (2002) showed that educational strategies were important to optimize management of minor illness. Also, a stringent law enforcement component, peer influence, including education for people on the perils of irrational use of medicines as a result of poor pharmacy prescription, needs to be further studied and addressed. (Chuc et al., 2002; Pham et al., 2013). Therefore, in future studies it will be important to explore the effectiveness of training or tools used by pharmacists to manage minor illness and reduce health risks.

Several criteria were reported as relevant to pharmacists' decisions to refer patients to medical practices or other services. According to Hassell and colleagues, pharmacists were considered a "filter" to the general practitioner: someone who could advise a visit to the doctor if necessary (Hassell et al., 1997). This is probably because pharmacists can assess the severity of the complaint and risk factors (Krishnan et al., 2000; Westerlund et al., 2003; Rutter et al., 2004; Alte et al., 2007; Driesen et

al., 2009; Mehuys et al., 2009). Although these competencies do qualify pharmacists to provide treatments or referrals, studies do not address whether pharmacist referral to medical consultation is indeed necessary for a particular patient (Berih et al., 1989; Krishnan et al., 2000; Westerlund et al., 2003; Rutter et al., 2004; Chui et al., 2005; Alte et al., 2007; Driesen et al., 2009; Saengcharoen et al., 2010). In the future, researchers need to design studies that consider medical opinions about community pharmacist intervention.

One of the key findings of this study was that pharmacists selected non-prescription medicines based on protocols or the patient's previous experiences with the medicine (Westerlund et al., 2003; Chui et al., 2005; Alte et al., 2007; Driesen et al., 2009; Mehuys et al., 2009). Protocols provide guidance to help pharmacists ascertain the need for the medication and provide individualized advice (NPA, 1989; Krishnan et al., 2000; Emmerton, 2009). Ideally, a pharmacist's decision to recommend non-prescription medicines should be evidence based and lead to safe and effective treatment (Krishnan et al., 2000). Future researchers can explore the utility of treatment protocols and guidelines at community pharmacies.

The type of pharmacist intervention varied considerably, probably because of the different minor illness presented. "Appropriate self-care advice" was defined as "the correct product and advice for the actual symptom, based on relevant questions by the pharmacy practitioner (Holtmann et al., 2011). Future studies would enable us to understand how pharmacist intervention change the natural course of a disease. However, to better understand and measure the impact of pharmacist counseling on self-medication outcomes, such studies must include a follow-up phase.

Positive outcomes were reported, including patient satisfaction with the pharmacist's services (Krishnan et al., 2000; Westerlund et al., 2003; Chui et al., 2005), and symptom relief (Westerlund et al., 2003; Mehuys et al., 2009). However, researchers cannot prove whether these positive outcomes are related to use of the non-prescription medicines or adherence to pharmacist advice (Berih et al., 1989; Rutter et al., 2004; Chui et al., 2005; Alte et al., 2007; Driesen et al., 2009). Because of the ongoing changes in healthcare systems, it is essential that researchers not ignore the role of the pharmacist in promoting health and preventing disease (Awad et al., 2010). Thus, research about pharmacist intervention for minor illness might include follow-up. Again, a qualitative approach to investigation of pharmacist counseling in self-medication might demonstrate that pharmacist's involvement improves patient health.

The inter-observer and intra-observer variability could not be measured in some studies because more than 1 simulated patient was included (Rutter et al., 2004; Alte et al., 2007). Variation in measurements could arise from various sources. In particular, an observer (i.e., simulated patient) could fail to repeat his or her own measurements when carrying out successive observations (i.e., simulations), or there may be disagreement between observers (Bland et al., 1996). Measurements may vary with choice of technique or with time. Future researchers could explore standardization of patient simulations to guarantee the reproducibility of measurements; long-term role-playing workshops could be conducted to standardize behavior during the interaction and minimize variability. Some authors assert that to reduce differences in how information obtained by simulated patients is recorded, video and audio records could be adopted (Weiss et al., 2010). Ethical issues related to consent of the pharmacist must be considered in this regard. Future researchers must not ignore the limitations of simulated patients, even if the same examiner and measuring techniques are used. Furthermore, these aspects are not applicable to studies intended to simulate different scenarios and symptoms.

Studies must distinguish between pharmacists and others pharmacy personnel to avoid reporting inaccurate results (Driesen et al., 2009; Saengcharoen et al., 2010). Equally, the advice concept lack was also a limitation found (Westerlund et al., 2003). These limitations are important because they influence quality outcomes and could generate interview bias. Other reported limitations related to the pharmacist's understanding of the necessity of referral and medical consultation (Mehuys et al., 2009), the extent of their consultation (Alte et al., 2007), and the quality of their service (Driesen et al., 2009). In future studies, these topics might be addressed with qualitative and quantitative approaches.

The present study is not without limitations. Firstly, the use of other relevant keywords, such as "pharmacist counseling", "patient consultation", "pharmacist recommendation", "simulated patient", "mystery shopping" may have yielded a larger sample. Xu et al. (2012) reviewed studies that used the simulated patient methodology, but it is not exclusive to this type of research. Secondly, researchers did not search, because access is unavailable in Brazil, the International Pharmaceutical Abstracts (IPAs) database, which indexes pharmacy-specific journals that are not included in any other database. Similarly, important articles that were not indexed in the selected databases would have been excluded. Hence, some studies that would have met inclusion criteria could have been left out of

the review. Finally, although articles worldwide are looking into the role of the community pharmacist in managing minor illness, non-English published articles were omitted, current findings are limited to countries which publish in the English language.

CONCLUSION

Most of the studies included in this systematic review evaluated pharmacist actions in providing nonprescription medicines to treat minor illness, the level of patient adherence, and the impact of pharmacist counseling on the patient's complaint. However, this revealed deficits in quality of some variables of the studies analyzed, such as: sample size calculations, participant age, and duration of pharmacist-patient interaction. The systematic review revealed that although pharmacist interventions occur, like indication of non prescription medicines and physician referral, these were few and were not evaluated for their impact on improving the minor illness because there is not a follow-up stage. As well as, the impact of patient adherence to pharmacist intervention on the minor illness relief was not observed and even the articles that deal with this verified a lack of practical measures that indicate their impact. Thus, even accounting for health promotion, pharmacist had not seized indeed that non-prescription medicines provision requires systematic and critical evaluation of the patient signs and symptoms beyond their pharmacotherapy needs. Therefore, it is necessary to improve research methods by combining qualitative and quantitative approaches to address the patient's perception of pharmacist attendance and the relationship on the assessment of complaints, the medicine indicated and clinical outcome, the economic, clinical e humanist impact of pharmacist interventions and the applicability of minor illness diagnosis and treatment protocols in community pharmacy.

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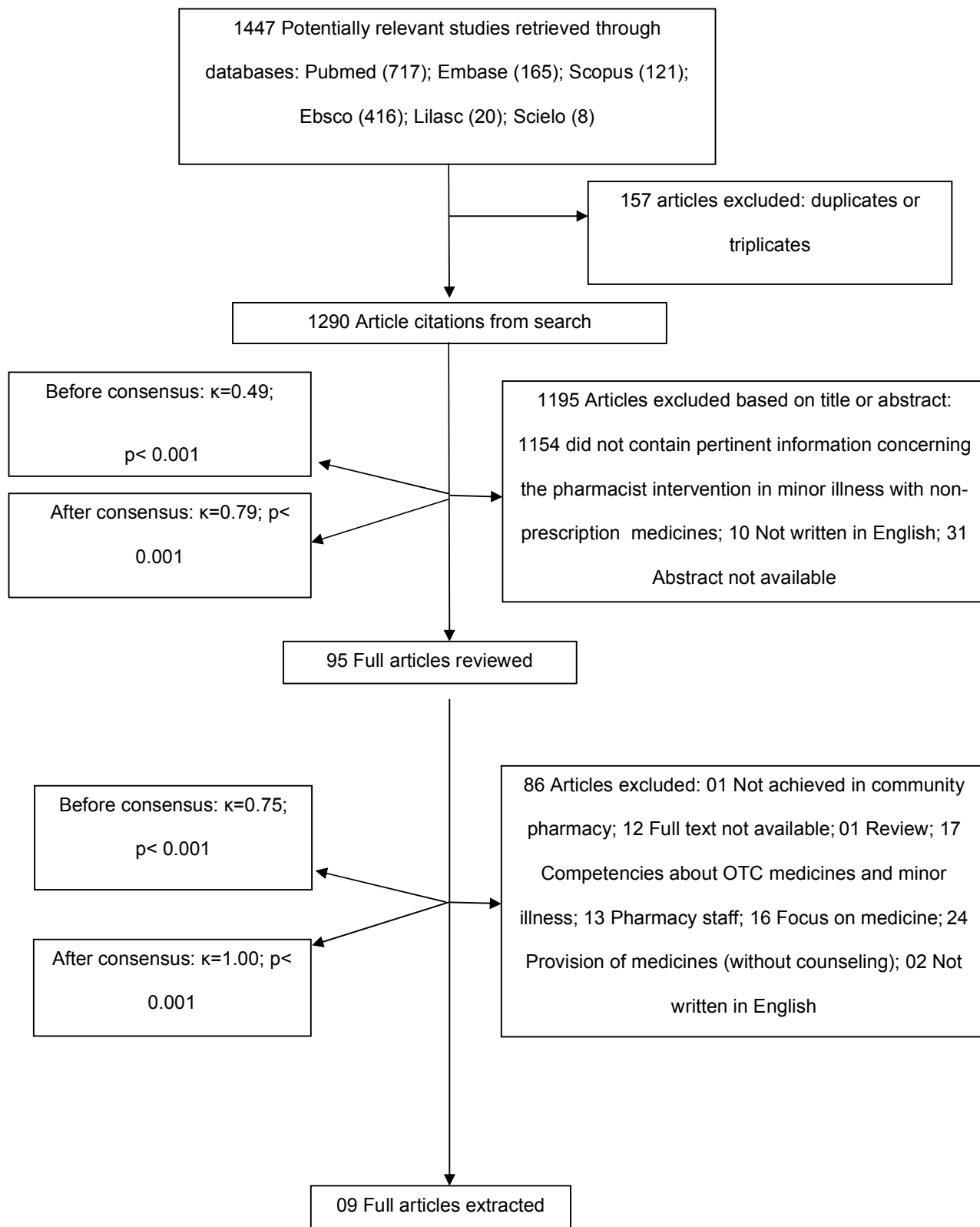


Figure 1: Study selection flowchart through literature search.

Table 1 General characteristics of studies (n = 9) included in the systematic review (community pharmacy settings)

Reference	Country	Participants	Sample size	Period (month)	Pharmacists' Consultation Duration (min)
Berih et al., 1989	Sudan	Pharmacist/ Simulated clients	63	01	NR ^a
Krishnan et al., 2000	Germany	Pharmacist/ Patients	36 SC ^b =15 CG ^c =21	07	NR ^a
Westerlund et al., 2003	Sweden	Pharmacist/ Patients	06	01	NR ^a
Rutter et al., 2004	England	Pharmacist/ Simulated clients	36	02	NR ^a
Chui et al., 2005	Singapore	Pharmacists/ Patients	44	01	<10
Alte et al., 2007	German	Pharmacist/ Simulated client	146	01	NR ^a
Driesen et al., 2009	Belgium	Pharmacist/ Simulated client	101	01	1.5 - 19
Mehuys et al., 2009	Belgium	Pharmacist/ Patients	NR ^a	06	NR ^a
Saengcharoen et al., 2010	Thailand	Pharmacy personnel	115	NR ^a	NR ^a

^aNR= not reported; ^bSG= study group; ^cCG= control group.

Table 2 Definition of pharmacist intervention (PI), type of MI managed, NPM advice, and characteristic of patient's adherence to the pharmacist's advice in the studies reviewed (n=09)

Reference	PI definition	MI managed	NPM advice	Patient's adherence to the pharmacist's advice
<i>Berih et al., 1989¹⁰⁷</i>	NR ^a	<i>Acute diarrhoea</i>	<i>ORS^b, and antidiarrhoeal</i>	NA ^c
<i>Krishnan et al., 2000¹⁰⁸</i>	Yes	<i>Dyspepsia</i>	NR ^a	Yes
<i>Westerlund et al., 2003¹⁹</i>	NR ^a	<i>Dyspepsia</i>	<i>Antacids, sodium alginate, histamine H2 - receptor antagonists, and proton-pump inhibitors</i>	Yes
<i>Rutter et al., 2004¹⁰⁹</i>	NR ^a	<i>Headache and abdominal discomfort</i>	<i>Acetaminophen, codeine phosphate, buclizine, pseudoephedrine, H2 -receptor antagonists, antacids, and bismuth subsalicylate</i>	NA ^c
<i>Chui et al., 2005¹¹⁰</i>	NR ^a	<i>Cough, gastric discomfort, cold and skin irritations</i>	NR ^a	Yes
<i>Alte et al., 2007¹¹¹</i>	Yes	<i>Headache</i>	<i>Aspirin, ibuprofen, acetaminophen, caffeine, and ascorbic acid</i>	NA ^c
<i>Driesen et al., 2009¹¹²</i>	Yes	<i>Acute diarrhoea</i>	<i>Saccharomyces boulardii, Lactobacillus acidophilus, smectite, domperidone, lactose-free milk, and food supplements</i>	NA ^c

<i>Mehuys et al., 2009</i> ¹¹³	Yes	<i>Upper GI symptoms</i>	<i>Domperidone, and antacid</i>	Yes					
<i>Saengcharoen et al., 2010</i> ¹¹⁴	NR ^a	<i>Acute diarrhoea</i>	<i>Pectin, kaolin, ORS^b, and antimotility</i>	NA ^c					
^a NR=	not	reported;	^b ORS=	oral	rehydration	solution;	^c NA=	not	applicable

Table 3 Methodological description of the studies (n = 9) included in the systematic review

Reference	Type of Study	Questions Asked	Reasons to Refer to Medical Practice or Other Services	Criteria to Indicate non-prescription medicines	Positive Outcomes	Declared Limitations
Berih et al., 1989 ³⁰	NR ^a	Symptoms	NR ^a	NR ^a	↓ antimicrobial use	NR ^a
Krishnan et al., 2000 ³¹	Randomized controlled trial	How long do the symptoms exist; the character and the severity of the symptoms; prior and current medication use; which actions already has taken; other medical problems	Direct Referral ^b and conditional referral ^c	NR ^a	↑ patient satisfaction with the pharmacist's services in self-medication	Sample size, Hawthorne effect, selection and response bias, unexplored the nature, the possible causes and the implications of the symptoms
Westerlund et al., 2003 ¹⁹	NR ^a	Is this the first time you have suffered from these symptoms? Do you have difficulty swallowing? Do you have dyspepsia symptoms daily?	Nearly daily problems for more than 3 weeks, difficulty swallowing, onset of dyspepsia symptoms after 45 years of age, and taking aspirin or NSAID ^d	Will you use this medication yourself? Have you used this medication before? How have you used this	↑ patient satisfaction with the visit to the pharmacy ↑ relief of dyspepsia symptoms	Not define advice

		For how long have you had the symptoms? Are you currently using nonprescription or prescription painkillers?		medication? How well do you think the medication has worked? For what ailments have you used, or do you intend to use, the medication?		
Rutter et al., 2004 ³²	Participant observation	Duration of the symptoms, nature and location of the pain, the presence of other symptoms, previous medical history, specific causes of the symptoms, aggravating or precipitating factors, pregnancy, previous medication tried	Previous episodes, duration of the symptoms, suspicious ADR ^e , symptom better treated by a doctor	NR ^a	Questions focus in general value of the symptom	Pharmacists refused interview, not measure interobserver variabilities, results not be generalized to other scenarios or pharmacist practicing in the same or other countries or practicing on another day

Chui et al., 2005 ³³	Cross-sectional	(prescribed or purchased) For whom the medication would be used and the age of the user, duration and characteristic of the symptoms, previous medical history and medication tried (prescribed or purchased)	NR ^a	Whether the symptoms could be relieved by the use of an OTC product	↑ patient satisfaction pharmacists' consultation Appropriate pharmacist information based on effectiveness and safety	Not document the intervention by the pharmacists
Alte et al., 2007 ³⁴	NR ^a	Duration, frequency, characteristic and nature of the symptoms, the presence of other symptoms, previous medical history, specific causes of the symptoms, aggravating or	Whether the headache persisted	Previous medication tried (prescribed or purchased), allergy, pregnancy, and breast-feed	↑ consultation offered without request ↑ professional status→ ↑ consultation quality (Appropriate pharmacist information based on effectiveness and safety)	Not measure inter- and intra-observer variability, not compare the extent of consultation, Hawthorne effect

		precipitating factors, medical consulting				
Driesen et al., 2009 ³⁵	Observational	The age of the patient, identification, nature and duration of the symptoms, actions, previous medication tried	Presence of severe dehydration, high fever, persistent vomiting, and uncertainty of diagnosis	Prevention and treatment of dehydration-oral rehydration solution, breast feeding, or normal feeding, S.b. ^f by about 24 h	↑ pharmacist's advice related to dehydration and dietary (questions focus in general value of the symptom)	Not guarantee the quality of pharmacy services, not generalized results, not distinguish between pharmaceutical technicians and pharmacists
Mehuys et al., 2009 ³⁶	Descriptive	Nature, frequency, duration, and presence of alarm symptoms, medical consulting, and medication use over the previous 12 months	Currently using aspirin, NSAIDs ^d , or PPIs ^g , and/or presenting with one or more alarm symptoms, and/or aged 50 years or older with recent-onset complaints	Dyspeptic symptoms NPA ^h and 10 mg domperidone 20 min before each meal Heartburn symptoms and dyspeptic symptoms –	↑ patient adherence to the pharmacist's referral advice ↑ symptom relief with NPM use ↑ patient adherence to the pharmacist's NPA ^h	Selection bias, not record the number of refusal and the reason, not measure the appropriateness of the referral decisions of the pharmacist, not check the necessity of the medical consultation

Saengcharoen et al., 2010 ³⁷	Questionnaire survey	The age of the patient; characteristics and frequency of stool; duration of, severity of, and associated symptoms; specific causes of the symptoms; dehydration-related symptoms; chronic diseases; and previous and/or current medication tried	NR ^a	NPA ^h antacid plus domperidone	NR ^a	↑ pharmacist's belief on NPM effect	Differences between SCs in performing and/or recording the information of the encounters, not generalized results, discrepancy related to the pharmacy personnel who fill in the questionnaires
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^aNR = not reported; ^bDefined as any verbal interaction between staff and customers, where they recommend the customer to immediately visit a doctor;

^cDefined as any verbal interaction between staff and customers, where they recommend the customer to see a doctor if the complain persisted after self treatment; ^dNSAID = non-steroidal anti-inflammatory drugs; ^eADR= adverse drug reaction; ^fS.b.= *Saccharomyces boulardii*; ^gPPI = proton-pump inhibitors;

^hNPA = non-pharmacologic advice

Table 4 Types of pharmacist interventions of the studies (n = 9) included in the systematic review

Pharmacist intervention	Frequency	%
Indication of an NPM	7	26.9
Physician referral	7	26.9
Indication of a non-drug approach	2	7.69
Indication of antimicrobial	2	7.69
Indication of oral rehydration solution	2	7.69
Dietary advice	2	7.69
Information concerning general health advice	1	3.84
Information about lifestyle changes	1	3.84
Information about product	1	3.84
Information about treatment	1	3.84

4.2 CAPÍTULO II - What do Brazilian community pharmacists know about self-medication for minor illnesses? a pilot study in the northeast of Brazil

WHAT DO BRAZILIAN COMMUNITY PHARMACISTS KNOW ABOUT SELF-MEDICATION FOR MINOR ILLNESSES? A PILOT STUDY IN THE NORTHEAST OF BRAZIL.

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Abstract

The benefits of self-medication are undeniable and include a decrease in the number of medical visits. In this work, among other objectives, it sought to describe the knowledge of a group of community pharmacists about minor illness and self-medication. This study was quantitative and qualitative, and took place between June and August 2012 in two groups of chain community pharmacies. All community pharmacists were interviewed face-to-face. Thirty-five community pharmacist completed the interview. Eighty-eight percent of the respondents were women and were aged above 25 years. A total of 88.8% said that they knew the definition of minor illness. Pharmacists that having studied management of minor illness as an undergraduate from private universities had more exposure to minor illness manager subject ($p = 0.0043$). Regarding the definition of minor illness, pharmacists cited specific parameters, such as duration of disease, and treatment or possible pharmacist intervention for symptoms, which showed a way to distinguish a minor symptom from a chronic disease. Pharmacists included detailed comments on particular aspects of the self-medication practice or highlighted medicine-specific characteristics. Findings indicated that community pharmacists have poor knowledge about minor illness that could explain the passive attitudes towards self-medication.

Keywords: Community pharmacist, self-medication, minor illness, knowledge, attitude.

INTRODUCTION

According to the literature, lack of knowledge throughout the population about the effects of non-prescription medicines allows for inappropriate selection of medications by patients as well as duplicate therapy, overdose, and other undesirable effects (Hughes et al.,

2002; NCPIE, 2003; Sallam et al., 2009; Cuzzolin and Benoni, 2010; Eickhoff et al., 2012). For these reasons, as non-prescription medicines contain potent active ingredients, they must be selected, used, and monitored with the same degree of care as with prescribed medicines (Eickhoff et al., 2012). However, the benefits of self-medication with non-prescription medicines are undeniable, and include a decrease in the number of medical visits per year, increased patient autonomy, and reduced costs within the healthcare system (Hughes et al., 2001; Brass et al., 2001).

The practice of self-medication arises when a patient perceives their clinical condition as a minor illness (Sallam et al., 2009), as well as the absence of health risks associated with non-prescription medicines (Covington, 2006). For this reason, the World Health Organization (WHO, 1998) suggests that responsible self-medication is a key parameter for self-care. However, studies claim that the benefits of self-medication are maximized when pharmacists apply their clinical skills, since the pharmacy is often the first place that patients seek for information about medicines (Benrimoj et al., 2008; Wilbur et al., 2010; Cuzzolin and Benoni, 2010; Major and Vincze, 2010; Major and Vincze, 2010).

In practice, the pharmacist must be encouraged to ask patients about the characteristics of their complaints when dispensing medicines (Cuzzolin and Benoni, 2010). Moreover, the pharmacist assesses complaints and indicates drugs for treatment of health problems (Cuzzolin and Benoni, 2010; Sallam et al., 2009; Major and Vincze, 2010; McConaha et al., 2013). The ability of pharmacists to effectively persuade patients to make appropriate choices is dependent upon how well they can help the patient understand and accept their diagnoses, the necessity for therapeutic processes, and on how well the patient can remember the advice and recommendations of the doctor or pharmacist (Major and Vincze, 2010).

Alternatively, community pharmacies in Latin America, especially in Brazil, have professionals without any specific training in health care that guide patients through the

selection and use of medicines (Kroeger et al., 2001; Turner et al., 2003; Bastos and Caetano, 2010). Despite this situation, patients have insufficient knowledge of medicines, and therefore, pharmacists must meet this social need. According to Bastos and Caetano (2010), there is a gap between recognition and concrete attitudes of pharmacist activities within the community pharmacy.

In Brazil, with the increasing presence of pharmacists in private pharmacies, the demand for counseling (mainly for non-prescription drugs) has grown in recent years (Araújo-Júnior and Vicentini, 2007; Andrade et al., 2012; Galato et al., 2012). However, there are no national statistics on the proportion of pharmacies that provide cognitive services (de Castro and Correr, 2007). Furthermore, most Schools of Pharmacy in Brazil are yet to implement clinical skills in their curriculum, despite the National Guidelines for Undergraduate Education in Pharmacy (Brazil, 2002) requirement to include formal training as an integral part of the pharmacy curriculum (Mesquita et al., 2010).

In Brazil, there are few studies focused on the perception of the pharmacist about the use of non-prescription medicines for management of minor illness, joint self-medication. The objective of this study is to describe the knowledge of a group of community pharmacists about minor illness and self-medication.

METHODS

Study design

This study was quantitative (cross sectional) and qualitative (content analysis), and was conducted using a structured interview technique. A simple thematic analysis was applied to identify key themes (Taylor and Bogdan, 1998). Themes were then quantified to validate impressions. The study took place between June and August 2012. All interviews were conducted in two groups of chain community pharmacies in Aracaju, Brazil. These

community pharmacies were representative of different geographical areas within city. Approval for this study was granted by the Sergipe Federal University Hospital Ethics Committee.

Samples size

Prior to the study, we conducted a sample size calculation with a finite population adjustment ($N = 43$), and assumed proportions of $P = 0.16$ (Hammond et al., 2004). Approximately 36 community pharmacists (CPs) were necessary to obtain two-sided 95% confidence intervals for single proportions, while extending five percentage points from observed proportions. It is important to emphasize that the sample was for convenience.

Participants

All CPs in the two groups of chain community pharmacies were eligible for participation. In consecutive order, these CPs were invited to participate in the study if they fulfilled the following inclusion criteria: age ≥ 21 years, present in the pharmacy during the interviewer's visit, and willing to participate in the research. This study excluded pharmacists who were absent during the two visits by the interviewer, pharmacists based in hospital or independent pharmacies, and individuals who were not pharmacists, as identified by the interviewer.

CPs were informed that the questionnaire regarded non-prescription medicines and minor illness. They were also informed that an audio and video recorded simulated patient visit would occur after one month of the interview. Participants who agreed to participate answered the questionnaire and complied with the simulated patient visit. All participants gave written informed consent.

Data collection

The interviewer, who was a pharmacy student, responsible for all data collection wore badges to identify herself as a researcher from Federal University of Sergipe. She visited

pharmacies twice each day from Monday to Friday, in the morning and afternoon. Thus, 23 pharmacies were visited over 46 visits. To help the interviewer understand the purpose and design of the study, a voice-recorded PowerPoint presentation was prepared and presented by the principal researcher before the study began. This step was taken to familiarize the interviewer with interviewing skills, and to facilitate complete documentation of the study data.

The questionnaire was prepared, tested, evaluated, and adjusted based on a pilot study with a small sample of CPs ($n = 10$); these data were not included in the final analysis. The questionnaire was administered in a private area of the community pharmacy, and lasted 10 to 15 minutes. If the CP was not at the pharmacy, the interviewer visited again one week later.

To avoid inappropriate compilation or misinterpretation of results, CPs were interviewed in person. This interviewer-administered approach is believed to provide more reliable and complete information than a self-administered questionnaire, which often results in inappropriate compilation and misinterpretation of the items (Kelsey et al., 1996).

The questionnaire consisted of 19 open and closed questions that included demographic data such as age, gender, education, occupation, and years of work in pharmacy. To assess knowledge about laws regarding pharmacists' role in self-medication, perception about minor illness, and self-medication, the participants were asked the following questions: "Do you know any laws that allow pharmacists to indicate non-prescription medicines? If yes, cite the law."; "Do you know what a minor illness is? If yes, cite an example"; "Can you define what a minor illness is?"; "how do you handle patients who self-medicated and ask for pharmaceutical counseling?". These two last questions were evaluated by content analysis.

Data analyses

Responses were coded and entered into the WHO Word Processing Database and Statistics Program for Public Health Epi Info, version 3.0, software package for descriptive

statistical analysis (CDC, 2013). Associations between variables were mainly analyzed by cross tabulating dependent (management of minor illness as an undergraduate) and independent variables (type of university and graduation time). Fisher exact tests were used and differences were considered to be statistically significant, if probability (p) was less than 0.05. The results are presented as frequencies and percentages. In a few cases, participants failed to answer every question, resulting in missing data. Missing data were not estimated or used in the analyses.

The content analysis method used in this research involves studying the vocalizations of people, not their thoughts, intentions, emotions, beliefs, or life experiences (Ostermann and Souza, 2009). This set of analysis techniques focuses on systematic and objective procedures for the inference of knowledge (Bardin, 2004). From the vocalizations were extracted meaning cores, and these in turn were classified so as to give rise to themes.

RESULTS

A total of 46 CPs were contacted during the study. Eleven CPs refused to participate and were excluded, resulting in 35 completed interviews. Eighty-eight percent (n = 30) of the respondents were women aged above 25 years (77.7%) (mean = 30.2; SD = 7.3), and 69.4% had graduated less than six years before this study (Table 1). The mean work experience in pharmacy was 4.4 years (range: 0-20 years).

Table 1 also demonstrates that 60% of CPs graduated from a private university and focused on clinical pharmacology (42.1%), and clinical and hospital pharmacy (21%) after graduation. The results showed that 37.1% of CPs had minor illness management when they graduated, and of these, 61.5% used the term *pharmaceutical semiology*. This discipline involves the management of minor illnesses with non-prescription medicines.

INSERT TABLE 1

CPs were asked to define the term "minor illness." A total of 88.8% said they knew the definition (Table 2), and from a total of 41 minor illnesses cited, fever (20%), headache (17%), and flu (10%) were pointed out as the most frequent examples (Figure 1).

INSERT FIGURE 1

Most CPs (54.3%) did not have legislative knowledge about minor illness management. On the other hand, among those who did have this knowledge (45.7%), 62.5% did not know the law number, and 31.25% cited the law as nº 44/2009 (Table 2). From a total of 57 sources of information cited, 91.4% of the CPs have used one or more during medication dispensing. Of these, 22.8% used the Dictionary of Pharmaceutical Specialties ("Dicionário de Especialidades Farmacêuticas" - DEF), 21% used Vademecum, and 17.5% used the Guanabara Therapeutic Dictionary (Table 2).

INSERT TABLE 2

Table 3 shows the factors that influence CPs' contact with the subject of minor illness subject at the time of graduation. Twelve (92.3%) pharmacists stated type of university to be a positive influencing factor. When compared with their colleagues, pharmacists who graduate from a private university had more exposure to this subject ($p = 0.004$) and pharmacists who graduated less than six years ago were 2.75 times more likely to have had the subject of minor illness management in their course ($p = 0.044$) (Table 3). No statistically significant relationship was found with the other variables.

INSERT TABLE 3

Pharmacists' definition of minor illness

Pharmacists who claimed to know what minor illness is, were asked to define the term. From the definitions gathered, two categories were identified, and eight sub-categories were extracted from the 22 comments made. On the other hand, ten pharmacists did not know what a minor illness is.

The categories and sub-categories identified, together with exemplar quotes, are shown in Table 4. Some sub-categories were related to specific categories, such as duration of disease (*"It is a set of symptoms or an isolated symptom, momentary"* - CP 30), and treatment or possible pharmacist intervention for symptoms (*"That we can intervene, are these symptoms"* - CP 24), which showed a specific way to distinguish a minor symptom from a chronic disease. However, the most prevalent comments related equally to two categories: emergence or manifestation (*"Minor symptom that manifested quickly"* - CP 12; *"Disease that develops rapidly with severe pain"* - CP 13), and severity (*"Symptoms that cause some discomfort but does not hinder a person's life"* - CP 15; *"The simple reactions occurring with health risk or death in debilitated patients or not"* - CP 35).

INSERT TABLE 4

Pharmacists' attitude toward self-medication

CPs also included more detailed comments about particular aspects of the self-medication practice or highlighted medicine-specific characteristics (Table 5). For example, some CPs reported collecting information from the patient or providing technical information regarding the drug's mechanism of action, when guiding self-medication (*"Explain how that*

drug will act in the body and its misuse which can occur in response to the organism” - CP 32; “I ask if he has allergies, if he has ever taken drugs, his age” - CP 3).

Others comments included screening complaint gravity, and then guides or forwards to the doctor, such as: *“Depends on the situation, if I can help I ask all the necessary questions and guide; if not, if it’s something more advanced, I point the doctor” - CP 15; “Depending on the problem I ask how old they are and how long they’ve had the problem. I advise if it’s not very serious, or if it is something chronic, I forward them to the doctor” - CP 35* (Table 5). Community pharmacists often refer the patient to a doctor (8.8%) or tell the patient to seek medical advice (5.8%). On this subject, one pharmacist noted that age group would be the determining factor about whether a patient could only be assessed by a physician: *“Depending on the disease, I refer to the physician. If the patient is elderly, I refer” - CP 24.* Other comments focused on banning the practice of self-medication despite pharmacist advice or referral to a doctor: *“I give directions, if the drug is needed, alright, otherwise I do not agree to explain” - CP 5; “First I tell the patient not to self-medicate, speak to look for medical advice” - CP 13* (Table 5). In contrast, there were pharmacists (5.8%) who could assess patients’ complaints in order to help them: *“If one asks for aid, I analyze his case, the symptoms, and check if the medication he is on hand is the most effective” - CP 26* (Table 5).

INSERT TABLE 5

DISCUSSION

The current study found a higher prevalence of female CPs, which is in accordance with theories of feminization of the profession in Brazil (Farina and Romano-Lieber, 2009). The study found a higher frequency of pharmacists in the age group of 20-29 years, but this does

not corroborate the findings of Farina and Romano-Lieber (2009) as well as those of Awad and Abahussain (2010). Although the average length of experience of pharmacists as practitioners was less than 5 years, studies showed that community pharmacists had more than 10 years of experience, as Anemblom et al (2004) Awad and Abahussain (2010) and Hanna and Hughes (2010) demonstrated. It is noteworthy that 73% of establishments registered in the Regional Councils of Pharmacy in Brazil are community pharmacies (BRASIL, 2012b). These findings support the idea that community pharmacies employ recently graduated pharmacists.

In Brazil, there are 416 pharmacy faculties, distributed at public and private universities (Oliveira-Sá, 2011). Most pharmacists (52.75%) graduated from private institutions, which corroborated the results obtained from Souza (2012). These institutions tend to be more receptive and include new subjects, such as pharmaceutical semiology, while the public institutions tend to be more conservative and are based on traditional disciplines (They have greater pressure to meet the National Curriculum Guidelines of Graduate in Pharmacy for a generalist pharmacy curriculum to be implemented, and tailored for the Brazilian Public Health System) (BRASIL, 2002).

According to Oliveira Sá (2011) the curriculum of some pharmacy courses at Federal Institutions of Higher Education on Brazil have an average workload comprised of 30.7% basic area focused courses (Biological and Health Sciences, and Physical Sciences) compared to 10.2% of Social Pharmacy and Clinic area courses. Yet pharmacists chose to specialize in the Clinical Pharmacy and Hospital Pharmacy areas in an attempt to meet the national demand in the field. This may result from deficiencies in training in these areas which, in turn, generates concern to pharmacists when the issue is patient clinical management. Thus, it can be stated that the CPs seeks to develop and improve their skills in identifying and minimizing

events that cause patient health risks, such as worsening of clinical symptoms or absence of early diagnosis.

In this study, we found that pharmacists had no exposure to subject about minor illness management. This reflects a technician model of Pharmacy graduation courses that do not provide clinical experiences in addressing acute or chronic medical conditions, health promotion activities, and education about the risks of irrational use of medicines. Studies have systematically pointed to failures in the provision of cognitive services by public and private community pharmacies, as well as in the training of the pharmacists in relation to clinical activities (de Castro and Correr, 2007). Training programs and treatment guidelines seem to have at least a transient positive effect on clinical performance. Likewise, half of the respondents pointed to the lack of algorithms and protocols for minor illness management in community pharmacies.

Westerlund et al.(2007) reported that clinical guidelines are of great importance in both standardizing and improving the quality of pharmacy advice to non-prescription drug consumers suffering from minor ailments. Considering that the process of decision making is complex (Hanna and Hughes, 2010), these tools are essential to assess the patient's clinical condition, and to selection the most appropriate treatment for an individual patient as supported by clinical evidence. According to Holtmann et al. (2011) the development of algorithms should serve as a basis for replication in more formal guideline recommendations. Thus, the use of therapeutic protocols that focus on disease pathophysiology and treatment provide the best choice of drug therapy, from obtaining detailed history of the complaint.

Our findings highlight that pharmacists do not have reliable sources of information for counseling patients. However, these results are similar to Franceschet and Rocha (2005), where the Dictionary of Pharmaceutical Specialties was used as a source of information in community pharmacies by 95.6% of pharmacists. However, this is not the best source of

information being an industry source, and has a conflict of interest. In Brazil, with the increasing presence of the pharmacists in private pharmacies, the demand for counseling (mainly for non-prescription drugs) has grown (de Castro and Correr, 2007). Therefore, the availability of reliable and scientifically-based sources of information, such as protocols and algorithms for decision making, will assist CPs in exploring the signs and symptoms, and differentiating those that require medical attention.

Many pharmacists had no knowledge of any Brazilian legislation concerning the management of minor illness. This finding confirms the need for implementation of teaching undergraduate disciplines that deal with pharmaceutical policies, given that the WHO (1998), and the Brazilian Federal Council of Pharmacy (2001) acknowledged the responsibility of the pharmacist in self-medication. Previous research has shown that the knowledge and attitudes that pharmacists have on regulatory aspects of how they should operate, and dispensing norms are unsatisfactory (Silva and Vieira, 2004) despite the norms of Good Dispensing Practices as edited by the Brazilian Federal Council of Pharmacy (CFF, 2001)

The study demonstrated that CPs cited minor symptoms examples when defined it that correspond to those reported in the medical literature (fever, pain, and diarrhea). Based on the study of Major and Vincze (2010) the most consumed non-prescription medicines were intended for the treatment of pain, fever, cold, and flu. Likewise, Victor et al (2008) showed that the habit of self-medication is associated with signs and symptoms of acute illnesses such as headache and fever. It was also noted that some CPs mentioned, on giving an example of a minor illness, that depending on the time of onset complaint, these symptoms are no longer considered to be minor, but indicative of a more serious disease (“Headache depending on how many days” - CP34; “Flu if not exceeds a period of 15 days” - CP 35). As Rutter et al (2004) demonstrated, parameters like this should be accompanied by further questions that

confirm and clarify the symptoms as well as allow the CPs to gain a complete picture of the patient's problem.

A group of pharmacists claimed to understand the term 'minor symptom'. However, they were unable to provide a definition of the term. Alternatively, some CPs were able to target parameters such as duration, frequency, and severity of the disease or symptom, but also noted that isolated components such as these would not alone classify a clinical complaint as acute or chronic ("It is a set of symptoms or an isolated symptom, momentary" - CP 30; "Pathological process non-recurring" - CP 29; "Are simplest diseases, symptoms that can be treated without going to the doctor" - CP 3). Some characteristics of the patient's complaint should be assessed by the pharmacist for decision making, such as age and sex of the patient, duration, frequency and severity of symptoms, and the presence of warning signs (Krishnan and Schaefer, 2000; Westerlund et al., 2003; Rutter et al., 2004; Chui and Li, 2005; Alte et al., 2007; Driesen and Vandenplas, 2009; Mehuys et al., 2009; Saengcharoen and Lerkiatbundit, 2010).

Most CP comments regarding self-medication included that the physician represents a form of professional anchoring regarding the responsibility for the patient. In other words, there is a social representation of the doctor as the only individual responsible for diagnosing and selecting treatment for illnesses, which reflects his ability to obtain the best clinical outcome for the patient. This assertion is corroborated by Weiss and Sutton (2009), who noted that some pharmacists, even with the legal mandate to prescribe, might still see themselves as subordinates within a medically dominated hierarchy, and feel the need to receive final approval from a medical colleague.

When the phrase "depending on..." was mentioned in the question, respondents also expressed their views about what situations determine their next step or attitude. This condition was particularly prevalent regarding CPs attitudes toward patients with specific

characteristics (“Depending, if I can indicate, I indicate. And also point out natural methods when possible, and if it is something more serious, I point the doctor, especially if they are elderly, pregnant or are a child” - CP 16; “Depending on the disease, I refer to the physician. If the patient is elderly, I refer” - CP 24). Krishan and Schaefer (2000) demonstrated that, depending on the problem, the pharmacist recommended that the patient visit a physician immediately (termed direct referral), or the pharmacist advised the patient to contact a physician in case symptoms persisted (termed conditional referral). Therefore, regardless of the clinical condition, the CP seeks to meet the needs of patients by acting guide and/or someone who suggest medicines, and/or someone who refers the patient to the doctor (“Depends on the situation, if I can help I ask all the necessary questions and guide; if not, if it’s something more advanced, I point the doctor” - CP 15).

Some CP comments were passive (“At first, my opinion is that he see a doctor” - CP 2; “Inform him to see a doctor to guide him” - CP 29), while others indicated a more active involvement and professional responsibility regarding self-medication. For example, some CPs assume that their role is to guide the patient, and at the same time regulate the use of the medicine (“I give directions, if the drug is needed, alright, otherwise I do not agree to explain” - CP 5). This can be explained by the findings of Weiss and Sutton (2009), in which CPs sell medicines over the counter to customers, and may engage in a discussion with the customer about what medicine is most appropriate for them.

Finally, it was observed that anamnesis is a key aspect that demonstrates the competence and performance of the professional, when assessing patient information. This can be shown by statements that indicate the need for patient evaluation before further decision-making regarding the most effective medicine for the patient (“If one asks for aid, I analyze his case, the symptoms, and check if the medication he is on hand is the most effective” - CP 26). It is important to note that this CP described briefly the prescription

process that should compulsorily list the most indicated, effective, safe, and convenient medicine for a clinical condition. Furthermore, Weiss and Sutton (2009) assumed that prescribing could be viewed as a complex series of processes with distinct tasks and decision points. The multiple terms used to describe prescribing generates uncertainty as to whether dose adjustments are prescriptions, and if refusal to dispense an incorrect prescription is also prescribing (Weiss and Sutton, 2009).

This research has a number of limitations. We recruited a self-selected group of community pharmacists who may not be representative of their professional colleagues. However, the sample size calculation was based on the number of network pharmacies under study. These network pharmacies were chosen because the pharmacist works during the opening hours of the pharmacy, but this is not reflective of the community pharmacy in Brazil. Moreover, the lack of a room for the interviews may have influenced the pharmacists' responses. To minimize this problem, interviews were conducted during the non-peak business hours (early morning and afternoon) and in the administrative area of the pharmacy. The interview was not recorded, which may have affected interpretations of the responses. However, the interviewer was trained to write down, and then repeat the answers to preserve the respondent's original intent. Finally, reflexivity was employed to improve the validity of the qualitative part of the research (Malterud, 2001). As part of the reflexivity, the interviewer debriefed with the fourth and the fifth researcher following interviews and discussed initial findings and interpretations.

CONCLUSION

In this study, the CPs analyzed had different characteristics—for example, they had studied at private universities, had exposure to the discipline of pharmaceutical semiology,

specialized in the clinical area, but did not have the correct perception of what was an evidence-based source of information.

Findings indicated that community pharmacists have poor knowledge about minor illness that could explain the passive attitudes towards self-medication. On the other hand, pharmacists presented several specific perceptions about minor illness, such as duration, severity, time of onset, and the possibility of treatment or pharmaceutical intervention. Moreover, some statements said that responsible self-medication advocates the assessment of patient clinical signs and symptoms culminating in pharmacist intervention that included patient orientation about the complaint and the treatment, and/or doctor referral if the patient presented as a risk.

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Table 1. Community pharmacist characteristic in relation to gender, age range, and education.
(Aracaju, June and August 2012).

Characteristics	Frequency	%
Gender		
Female	30	83.3
Male	5	13.8
Age range (complete years old)		
≤ 25	5	14.3
> 25	27	77.1
Not informed	3	8.5
Community pharmacy experience (years)		
≤ 5	25	71.4
> 5	10	28.6
Graduation		
Private University	21	60
Public University	14	40
Post-graduation		
Yes	19	54.3
No	16	45.7

Area of post-graduation (lato sensu)

Clinical Pharmacology	8	42.1
Clinical and hospital pharmacy	4	21
Dispensing pharmacy	2	10.5
Others	5	26.3

Having studied minor illness management during pharmacy graduation

Yes	13	37.1
No	21	60
Not know	1	2.8

Table 2. Frequency of minor illness definition and legislation knowledge, and types of information sources. (Aracaju, June to August 2012).

Variable	Frequency	%
Define minor illness		
Yes	31	88.6
No	4	11.4
Legislation knowledge		
Yes	16	45.7
No	19	54.3
Information Sources		
Yes	32	91.4
No	3	8.6
Type of information sources		
Dictionary of Pharmaceutical Specialties	13	22.8
Vade Mecum	12	21
Guanabara Therapeutic Dictionaty	10	17.5
Internet	5	8.8
Others	13	22.8

Table 3. Factors that influence the community pharmacists' exposure to minor illness subject during graduation. (Aracaju, June to August 2012).

Variables	Minor illness subject		Prevalence	RP ^a	p- valor ^b
	Yes	No	(%)		
Type of university					
Private	12	9	57.14	1.00	
Public	1	12	7.69	7.42	0.0043
Time range of graduation (years)					
≤ 5	12	12	50	1.00	
> 5	2	9	18.18	2.75	0.044

^a Prevalence ratio.

^b p value from Fisher exact Test.

Table 4. Categories and subcategories identified from pharmacists' responses about minor illness definition (Aracaju, Sergipe, Brazil, June to August 2012).

Category	Subcategory	Number of comments	Example
Disease	Duration	3	"It is one disease that is chronic" (CP 5); "Diseases which do not persist" (CP 28); "It is a set of symptoms or an isolated symptom, momentary" (CP 30)
	Emergence or Manifestation	4	"Disease that develops rapidly with severe pain" (CP 13); "These are diseases in the latest stage" (CP 10); "Sudden illness, which is not chronic" (CP 17); "Pains that appear suddenly" (CP 18)
	Frequency	1	"Pathological process non-recurring" (CP 29)
	Severity	4	"Are simplest diseases, symptoms that can be treated without going to the doctor" (CP 3); "Lightest symptoms, most common, easiest to treat, which may progress if handled wrong" (CP 25); "These diseases have a lower risk of severity" (CP 31); "The simple reactions occurring with health risk or death in debilitated patients or not" (CP 35)

Symptom	Treatment or possible pharmacist intervention	1	“That we can intervene, are these symptoms” (CP 24)
	Emergence or Manifestation	4	“Symptom immediacy”(CP 6); “Minor symptom that manifested quickly” (CP 12); “A symptom that feels at that moment, but can disappear on treatment” (CP 32); “Recent symptom recent”(CP 33)
	Frequency	1	“A symptom that is not constant” (CP 16)
	Severity	4	“Symptoms that cause some discomfort but does not hinder a person's life” (CP 15); “Are emergency symptoms that appear” (CP 20); “Are palliative symptoms that we can treat” (CP 21); “Are simple symptoms for which people come into the pharmacy" (CP 23)

Table 5. Themes identified from pharmacists' attitude about self-medication (Aracaju, Sergipe–Brazil, June to August 2012).

Guidance on self-medication 10	<p>“I make it clear the severity of self-medication” (CP 31); “I direct how it should medicate correctly” (CP 19); “I’ll help” (CP 18); “Give advice” (CP 7); “Explain how that drug will act in the body and its misuse which can occur in response to the organism” (CP 32); “Advise in the best way possible, check to see if the medicine he is using corresponds to what is appropriate” (CP 20); “I ask if he has allergies, if he has ever taken drugs, his age” (CP 3); “Looking for ways of creating awareness and consciousness of the correct way to use the medication” (CP 1); “I try to advise the best way to not affect it” (CP 10); “Listening to him, asking questions that may clarify the problem to be able to guide him better” (CP 12)</p>
Screening for severity, and guides or directs to the doctor 9	<p>“Depends on what it is: if it’s a medication associated with great risk, I advise him to see the doctor; if not, I give advice” (CP 14); “Depends on the medication: when it is an over-the-counter medicine, I guide; when it’s not, I refer to the doctor” (CP 11); “Depends. I advise depending on what the patient complains of, if it doesn’t improve, I recommend that he seek medical advice” (CP 6); “Depends on the situation, if I can help I ask all the necessary questions and guide; if not, if it’s something more advanced, I point the doctor” (CP 15); “Depending on the problem I ask how old they are and how long they’ve had the problem. I advise if it’s not very serious, or if</p>

		it is something chronic, I forward them to the doctor” (CP 35); “Depending on the situation, I forward it to the doctor, if not I advise. If they are elderly or are children, or if it is more serious, I forward them to the doctor” (CP 25); “I always seek medical advice or when something is palliative I guide him” (CP 17); “If it’s an over-the-counter medicine I guide, but if it is a prescription, I seek medical advice” (CP 4); “When it is a more serious problem I point the doctor, if it is a minor problem I guide” (CP 28)
Referring the patients to the doctor	3	“Depending on the disease, I refer to the physician. If the patient is elderly, I refer” (CP 24); “At first, my opinion is that he see a doctor” (CP 2); “Depending on what it is, I indicate that they call the doctor” (CP 34)
Directing the patients to seek medical advice	2	“Inform him to see a doctor to guide him” (CP 29); I ask him to go to the doctor” (CP 36)
Screening the severity, and indicate the medicine or guide to seek medical advice	2	“Depending, if I can indicate, I indicate. And also point out natural methods when possible, and if it is something more serious, I point the doctor, especially if they are elderly, pregnant or are a child” (CP 16); “Clarify that he should not, or if it should be used, e.g., if it’s for the flu, I indicate; if it’s anything more serious, I ask to call the doctor” (CP 27)
Advising patients	2	“Do the intervention, and advise to see a doctor” (CP 23); “Normally I check what it is, but if the patient is

before referring them to the doctor.		already making use (of medication), (then I ask them to) seek medical advice” (CP 30)
Advice or not allow 2 the patient get the medicine		“I give directions, if the drug is needed, alright, otherwise I do not agree to explain” (CP 5); “I try to guide, often tell him not to buy” (CP 22)
Prohibits self- 2 medication and forwards to the doctor		“First I tell the patient not to self-medicate, speak to look for medical advice” (CP 13); “I suggest that the patient stop taking, and seek medical advice” (CP 21)
Questioning patient 2 information— emphasis on anamnesis		“If one asks for aid, I analyze his case, the symptoms, and check if the medication he is on hand is the most effective” (CP 26); “I ask for information, and ask how long they have been feeling the symptoms” (CP 33)

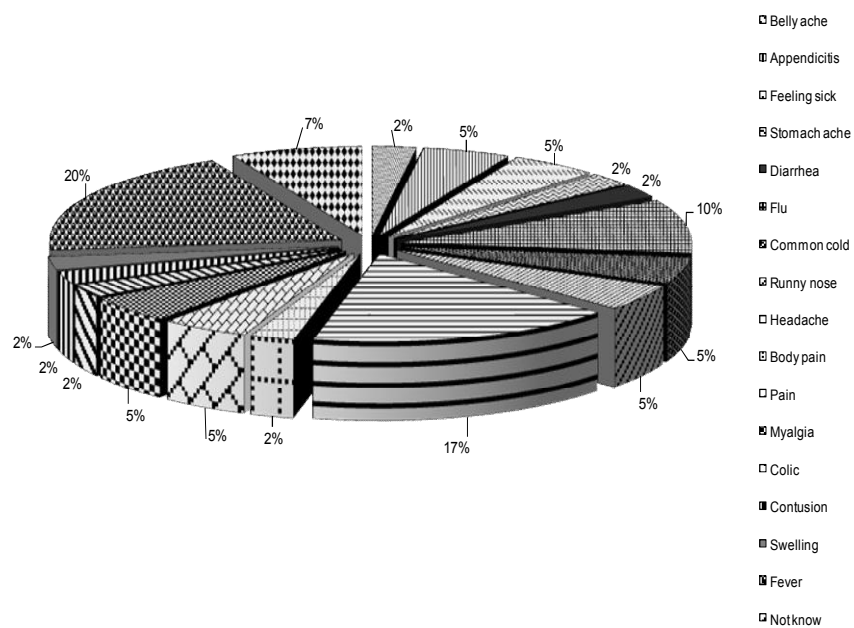


Figure 1. Frequency of the minor illness cited by the sample. (Aracaju, June to August 2012).

4.3 CAPÍTULO III - ASSESSMENT OF THE COUNSELLING PRACTICES OF COMMUNITY PHARMACISTS WITH SIMULATED PATIENTS WITH MINOR ILLNESS – A PILOT STUDY

ASSESSMENT OF THE COUNSELLING PRACTICES OF COMMUNITY PHARMACISTS WITH
SIMULATED PATIENTS WITH MINOR ILLNESS – A PILOT STUDY

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SUMMARY STATEMENT

- The standard of healthcare provided by the community pharmacists was generally low, especially regarding the assessment of the characteristics of the presented complaint (symptoms, time of onset of the complaint, associated symptoms, etc.). This could have hampered their recommendations for palliative treatments and/or referral to the doctor for careful evaluation of the complaint.
- The community pharmacists did not introduce his/her self appropriately, explain the purpose of the orientation, assessed whether the patient had any other medical conditions, review the patient's understanding, any real concerns, and/or potential patient problems. They did not provide much information about the safe and proper use of the non-prescription medicine and the need to seek the opinion of a medical consultant.

BACKGROUND

Studies have demonstrated that the practice of self-medication presents a possible risk of abuse and inappropriate use of medicines, which increases the incidence of drug-related problems and may compromise patient safety.^{1,2} However, with the availability of and easier access to a wider choice of diverse non-prescription medicines than before, it is important for the pharmacists to know that the right advice must be given when the patient seeks their help.³

According to the WHO guidelines,^{4,5} a community pharmacist (CP) must provide counselling to the consumers of non-prescription medicines and promote responsible self-medication. Counselling aim is 'to give the patient an opportunity to explore, discover and clarify ways of living more resourcefully and towards greater well-being'.⁶ Thus, pharmacists must maintain at a high standard of practice by ensuring safe, effective, and appropriate use of non-prescription medicines.^{7,8}

One approach to guarantee this quality and to provide continuing professional development for the CPs is by using the simulated patient (SP) technique to assess and improve practice.^{1,7-10,11,12} In the last decade, the SP technique has been used around the world, as an assessment and educational method, to identify issues in current pharmacy practice, to evaluate professional performance and to inform interventions to shape practice behaviour of the CPs.^{8,13-15}

According to Castro and Correr,¹⁶ no statistics are available on the proportion of pharmacies that provide cognitive services in Brazil. Furthermore, few studies have explored the performance of the CPs with reference to patient-centred cognitive services in community pharmacies.^{7,17,18} Thus, quality improvement

initiatives are needed for the responsible provision of self-medication, especially to fully integrate the Brazilian CPs into patient-centred cognitive services. Consequently, the aim of the present study was to assess the performance of the CPs in the management of the cases with minor symptoms, using non-prescription medicines.

METHODS

Study design

A cross-sectional design was employed and the data were collected from September to November 2012. The SP patient method was chosen to assess the practice behaviour of CPs in Brazil, as it allowed for observing of the pharmacists in their natural environment, uninfluenced by awareness that their behaviour was being observed. All simulations were conducted in two chains of community pharmacies in Aracaju. These community pharmacies were representative of different geographical areas within the city.

Sample size

Prior to the study, we conducted a sample size calculation with a finite population adjustment ($N = 43$) and assumed proportions of $P = 0.16$.¹⁹ Thus, approximately 36 CPs were necessary to obtain two-sided 95% confidence intervals for single proportions, while extending five percentage points from observed proportions. It is important to emphasize that the sample was for convenience.

The Laboratory of Teaching and Research in Social Pharmacy (LEPFS) on Federal University of Sergipe, Brazil, recruited the sample of pharmacies (a total of 43 CPs was contacted, and 40 accepted participate), based on the geographic location (metropolitan area), from the city of Aracaju in Brazil. Further, the sample consisted of 2 pharmacists from each of the selected pharmacies. Aracaju is the capital of the State of Sergipe in Brazil, located in the north-eastern part of the country, with a population of approximately 571,000 inhabitants, which represents approximately 33% of the state population. There are 195 pharmacies in the Aracaju metropolitan area (chain and independent community pharmacies). Approval for this study was granted by the Sergipe Federal University Ethics Committee.

Participants

The cough and rib pain, and sinusitis related counselling was assessed using the SP method. The LEPFS and two private community pharmacy chains signed an agreement to participate and cooperate in the study. Following the agreement with the management, the CPs were invited to participate in the study if they fulfilled the following inclusion criteria: age ≥ 21 years, were present in the pharmacy during the SP visit, and were willing to voluntarily participate in the study. This study excluded the pharmacists who were absent during the

two visits by the SP, the pharmacists who were based in a hospital or independent pharmacies, and individuals who were not pharmacists, as identified by the SP.

The CPs were informed that an audio and video-recorded SP visit would be conducted some months of the invitation made by personal contact, to eliminate the behavioural bias over time. The participants who agreed to participate provided written informed consent. The participants were informed that they could refuse to participate in the study at any time, and that the data gathered would be kept anonymous and strictly confidential. The details of the scenarios and the identity of the SP were not disclosed to the participants.

The researchers explained to the eligible CPs that the study had a formalized feedback system for detecting the SP visits, in which the CPs would have to telephone the researchers when they suspected that an SP visit had occurred, and provide the date, time, and drug dispensed in the suspected visit. Based on this information, the researchers could determine if a visit had been detected and consequently, eliminate it from further study.

Pilot Study

A pilot study was carried out with 10 CPs who worked in the pharmacies that were not a part of the study sample. The pilot study helped detect the possible shortcomings in the methodology. The SPs visited the pharmacy using the two scenarios, i.e., cough and rib pain, and sinusitis, in order to test the scenarios and the two SPs. In an interview that followed the last SP visit, the participating CPs stated that they did not detect any of the SP visits. Thus, no significant deficiencies were identified in the constructed methodology for the present study.

Scenarios

One pregnant woman and a female pharmacy student were trained to enact one of the scenarios, in an 8-hours training session. During the training, they were informed about the methodology, the scenario, and the rules of approaching the CPs. A considerable part of the training involved role-playing, where one of the researchers acted as a pharmacist. The SPs enacted the scenario, which were audio recorded to enable analysis and the further improvement of their performance. Based on their performance, further instructions and advice was given. The SPs were informed about the ethical code designed for this study, in order to ensure the anonymity of the participating individuals and to protect the integrity of the data obtained.

After entering the participating pharmacies, the SPs either requested the purchase of a non-prescription medicine or the treatment for a symptom according to the scenario used. The scenarios dealt with self-medication for a cough and rib pain, and sinusitis. The details of the scenarios have been presented in Table 1.

The SPs would visit the participating pharmacy, ask to see the pharmacist and then seek advice, either for the treatment of a persistent cough accompanied by rib pain, or a sinusitis complaint (sore throat, runny nose, itchy throat, sneezing, nasal congestion and facial pain) (Table 1).

In scenario 1, the SP was instructed to request treatment for a cough and not provide any further information unless requested by the pharmacist. On the other hand, in scenario 2, the SP was instructed to communicate the symptoms and ask or tell anything to the pharmacist even if they were not requested for the same by the CP. The scenarios were designed to assess the willingness and the ability of the CP to offer appropriate advice, and the ability to solicit appropriate information to identify a hazardous health situation.

An expert panel, comprising four clinical pharmacists, was established to review current clinical evidence in relation to the clinical scenario used in the study, and to establish what constitutes a reasonable or desirable outcome in terms of the practice behaviour of Brazilian CPs. In both scenarios, they established that if the CP chooses to indicate a medicine, all the information necessary to ensure the rational use of the same should be provided to the SP. This information includes, the name of the drug, indication, dose, dosage, the mode of administration, the duration of treatment, the onset of action, major adverse reactions and drug interactions, action to be taken if reactions occur, storage of the medicine, and details about when to seek medical attention.

In response to Scenario 1, the panel specified that the pharmacist should explore the patient's history, characteristics of the complaint (including conditions other than the pregnancy), medicines the patient is taking currently, and medicines that had already been tried to treat the cough. They also deemed it important that the CP is able to establish if the rib pain was likely to be related to the persistent cough. Further, the expert panel agreed that the scenario warranted the recommendation of a medical consult, and non-pharmacological therapies, such as increasing liquid intake, humidifying the air by using humidifiers, vaporizers, or hanging wet towels in the room, avoiding polluted environments or cigarette smoke, and using honey (if not diabetic) for the cough.

For Scenario 2, the expert panel pointed out that the CP, as in scenario 1, should explore the patient's history and characteristics of the complaint (the frequency and duration of the symptoms, the nature and location of the pain, the presence of other symptoms, the specific causes of the symptoms, and the aggravating or precipitating factors). In addition, the CP should also consider the presence of any other clinical conditions, the medicines the patient may be taking currently, and the medicines that had already been tried to treat the complaint. Finally, the CP should also be able to establish whether the facial pain was likely to be related to sinusitis and then indicate a non-prescription medicine as a palliative, and emphasize the need for medical consultation because of the suspicion of a case of sinusitis. The panel also recommended that the CP should be

able to provide counselling regarding alternatives for the relief of symptoms prior to medical consultation, such as, using saline solution in the form of nasal drops and the correct form of administering the same, the use of sodium bicarbonate in warm water to gargle for sore throat relief, and recommend the adoption of non-pharmacological measures such as cleaning the air conditioning or fan, taking adequate rest and sufficient hydration.

Documenting the counselling process

On entering the pharmacy, the SP asked to speak directly with the pharmacist. The conversation was initiated by the SP, by stating her symptoms. The duration of the time spent on counselling was measured from the moment the patient was received by the pharmacist, until the moment she left the community pharmacy. During each visit, the SP recorded the interaction with the CP using a hidden micro camera. Two investigators analysed the recorded interactions. These investigators were pharmacists, with the knowledge of case resolution, had undergone theory and practical training in counselling. They assessed the clinical skills of the participants with the instrument developed by the United States Pharmacopeia (USP) called 'Medication Counseling Behavior Guidelines' (MCBG) and validated to Portuguese language through a consensus method based on registration of existing assessment tools for patient education.¹⁸ It is considered the first attempt to assess the pharmacists' skills of patient education, within the context of communication between pharmacists and patients.²⁰ Currently, it is considered the most comprehensive model for assessing patient education for its completeness in evaluating the pharmacist's competency in patient care.^{20,21,22}

According to the USP model, each patient counselling encounter comprises four parts: 1) the introduction, which aims at assessing the patient's information needs; 2) the content of the information provided, that should be customized according to the needs assessment; 3) the concluding part which should focus on ensuring that the patient has understood the information provided; and 4) the communication techniques that are needed in each step of the process. It was developed by specialists to facilitate learning and self-improvement of pharmacists. The validity and suitability of the USP guidelines has been tested in the context of community pharmacy (Cronbach's alpha for the whole original scale was 0.91).²³

This tool is composed of 35 structured items divided into four categories: introduction, content, process, and completion of orientation. Each item is evaluated according to the pharmacist's performance in the interaction with the SP, measured on a ten-point Likert type scale (1= not done, 2= poor, 3–5= regular, 6–7= good, and 8–10= excellent). It is important to highlight that one item from the category-content of orientation, was excluded from the study (tell the patient (or agent) when he/she should go back to get the medicine again),

because it could not be adapted to the proposed scenarios in the present study. The discrepancies in observation between the investigators were resolved through consensus. Thus, the audio-visual records were reviewed repeatedly and discussed until a consensus was reached.

Statistical analysis

Descriptive statistics were used to analyse most of the variables. The results were presented using mean \pm standard deviation (SD), frequency, or proportion. Statistical analysis was performed using the Biostat, version 5.0. Since the Shapiro-Wilk test did not show a normal distribution in the data, the non-parametric test Wilcoxon rank sum, with alpha set at $p < 0.05$, was used to compare the CP questionnaire ratings between the two scenarios.

RESULTS

Of the 43 CPs contacted, 40 (93%) agreed to participate in the current study. The pharmacies were located in the metropolitan area in different districts of the city. None of the SP visits was excluded from the analysis as none of the CPs called to inform the researchers of a suspected SP visit during the study. The two scenarios were enacted for all the 40 participating CPs. Thus, 80 simulations were conducted. Most of the CPs were female in both the scenarios (90% in the cough scenario and 95% in the sinusitis scenario). Altogether, the average time spent on the counselling of the SP was 91.31 seconds or 1.52 minutes ($SD \pm 68.63$ seconds), and the lowest and highest duration spent on counselling was 18 seconds and 554 seconds, respectively. The pregnant SP with dry cough and rib pain had to wait for an average of 27.2 seconds before being served in 27.5% of the visits. On the other hand, the SP presenting with sinusitis had to wait for an average of 51.5 seconds before being served in 45% of the visits. The pharmacists provided some form of counselling without being prompted, in 85.0 % of the visits in the scenario involving the pregnant SP with cough and rib pain, and in 92.5% of the visits in the scenario involving the SP with sinusitis.

It was observed that 20% (8/40) of the CPs did not perceive that the SP was pregnant. On the other hand, 12.5% (5/40) observed that she was pregnant, and subsequently changed the intervention by referring the SP to the doctor. The most commonly recommended medicines for 37.5% (15/40) of the CPs in Scenario 1 were, expectorants (oxomomezanin + guaifenesin + potassium iodide) (1), peripheral antitussive (dropropizin) (4), central antitussive (cloperastin) (1), herbal remedies (honey and cress) (2), and tablets (benzocaine + cetilpiridíneo) (2). Apart from these, some pharmacists recommend topical medications to relieve the rib pain, i.e. diethylamine hydrochloride gel (1), or methyl salicylate + camphor + menthol (1), or recommended an oral

antiinflammatory (paracetamol, ibuprofen) (2) and associated medication (caffeine, carisoprodol, diclofenac, and paracetamol) (1).

It was noted that 72.5% (29/40) of the CPs recommend that the SP should visit a clinician, and only 10% (4/40) highlighted the adoption of non-pharmacological measures like ginger lozenge (2) and aerosolized saline solution (1) for the cough, and warm moist compresses for the pain (1). Among the CPs who recommended drugs for the cough, 26.67% (4/15) also recommended medical consultation, and 6.67% (1/15) suggested the adoption of non-pharmacological measures such as warm moist compresses to relieve the pain in the ribs.

With reference to Scenario 2 with the young woman with sinusitis, 60% (24/40) of the CPs recommended treatment with non-prescription medicines. Further, only 37.5% (15/40) of them mentioned the name of the medicines [26.7% (4/15) paracetamol, 13.3% (2/15) maintenance dipyrrone therapy, 6.7% (1/15) diclofenac, 6.7% (1/15) ibuprofen, and 6.7% (1/15) ketoprofen, with associated drugs like 6.7% (1/15) paracetamol + pseudoephedrine, 6.7% (1/15) paracetamol + ephedrine, 6.7% (1/15) paracetamol + caffeine, 6.7% (1/15) caffeine + dipyrrone + chlorphenamine, and 13.3% (2/15) phenylephrine + brompheniramine]. One of the CPs indicated a combination of dexclofeniramina + betamethasone. Overall, 85% of the CPs recommended consulting a physician to ensure accurate diagnosis and treatment that could include antibiotics. Among the CPs who indicated non-prescription medicines, 83.3% (20/24) mentioned the need for medical consultation. Interestingly, none of the CPs recommended any non-pharmacological measures for this SP.

Importantly, 65% (26/40) of CPs identified the sinusitis by asking the SP of Scenario 2 about the characteristics of the complaints, such as, sneezing, rhinorrhoea, nasal congestion, presence and appearance of the secretion, headache, facial pain, fever, and cough. Further, they investigated the location of the pain, the duration and frequency of the symptoms, previous experience with the complaint, and if changes in the weather or temperature caused the nasal congestion (precipitating factor). However, one CP suggested the possibility of dengue, because the SP reported to have a headache and prostration. Among these CP, all showed paranasal sinus, especially the maxillary, when generating the diagnostic hypothesis of sinusitis case.

Part 1 - Introduction to the orientation

The MCBG tool had eight items in the section on introduction. For Scenario 1, it was observed that none of the CPs (100%) had fulfilled the first item, 'explain the purpose of the orientation'. With reference to the other seven items, they had been performed by a low proportion of the CPs, to a level ranging from satisfactory to excellent. Specifically, the following behaviours were observed: 'at the beginning, leads the orientation,

presenting and identifying who the patient is or the person responsible for him/her' (10%), 'reviewed the patient's drug request before the orientation (17.5%)', and 'obtained preliminary and pertinent information related to the drug request' (55%). Details of the findings have been presented in Table 2.

In Scenario 2, none of the CPs (100%) were observed to exhibit the behaviours mentioned in two of the items, specifically, 'explain the purpose of the orientation', and 'warned the patient about the use of other drugs or substances, including non-prescription medicines, and herbal and alcoholic beverages, which could interact with the requested drug (increasing, decreasing or cancelling its action)'. Similar to the findings in Scenario 1, a low proportion of the CPs exhibited the rest of the behaviours assessed to a satisfactory or excellent level. Specifically, the following behaviours were observed: 'at the beginning, leads the orientation, presenting and identifying who the patient is or who is responsible for him/her' (5%), 'reviewed the drug request before the orientation' (45%), and 'obtained preliminary and pertinent information related to the request for the drug' (5%). Details of the findings have been presented in Table 2.

Part 2 – The content of the orientation

Concerning the behaviours related to the content of the orientation, out of the 14 items or behaviours in the MCBG tool, five behaviours were not observed in any of the CPs (100%) in Scenario 1. These were, 'explained how long it takes for the drug to take effect', 'discussed the recommendations for storage and additional instructions (e.g. shake well, keep refrigerated)', 'emphasized the benefits of using the medication as directed', 'discussed the significant interactions between drug-drug, drug-food, and drug-disease', and explained in precise terms what to do if the patient misses a dose. Further, a low proportion of the CPs were observed to exhibit the other behaviours to a satisfactory or excellent level. Specifically, these the following behaviours were observed: 'discussed the name and the indication of the drug' (22.5%), 'explained the dosing, including the time of use and duration of therapy, when appropriate' (10%), and 'assisted the patient (or agent) to develop a care plan to incorporate into his/her routine pharmacotherapy' (2.5%). Details of the findings have been presented in Table 3.

Again, the findings with reference to the content of the orientation in Scenario 2 were similar to those in Scenario 1. The analysis revealed that none of the CPs (100%) was observed to exhibit the behaviour measured in six of the 14 items. Some of these items were: 'discussed storage recommendations, ancillary instructions (e.g., shake well, refrigerate, etc.)', 'discussed the precautions associated with the medication (e.g. avoid operating machinery or driving)', 'explained in precise terms what to do if the patient misses a dose', and 'discussed with the patient (or agent) the potential problems in taking your medicine as directed (e.g. cost,

access)’. Note that one of the items were the same as in Scenario 1. Further, a low proportion of the CPs exhibited the behaviours assessed in the rest of the items to a satisfactory or excellent level. Specifically, these the following behaviours were observed: ‘discussed the name and the indication of the drug’ (37.5%), ‘explained the dosing, including the time of use and duration of therapy, when appropriate’ (20%), and ‘explained how long it takes for the drug to take effect’ (5%). Details of the findings have been presented in Table 3.

Part 3 —The orientation process

The analysis of the process items revealed that, in Scenario 1, out of the 12 items, one behaviour were not exhibited 100% of the CPs. This was, ‘investigated additional information (e.g. lifestyle, beliefs)’. However, contrary to the findings of the previously discussed sections of the MCBG tool, for most of the remaining items, a high proportion of the CPs exhibited the behaviour assessed, to a satisfactory or excellent level. Specifically, these the following behaviours were observed: ‘used accessible language with the patient (agent)’ (75%), ‘used the knowledge based on the literature, to support patient (or agent) orientation’ (30%), ‘responded with understanding and empathy’ (50%), ‘the facts and concepts were presented in a logical order’ (52.5%), and ‘maintained control and direction of the orientation’ (85%). Details of the findings have been presented in Table 4.

In scenario 2, 100% of the CPs did not exhibit the behaviour assessed in the same item as those discussed for Scenario 1. With reference to the behaviours exhibited to a satisfactory or excellent level, most CPs were found to exhibit such behaviours: ‘used accessible language with the patient (or agent)’ (67.5%), ‘used the knowledge based on the literature to support patient (or agent) orientation’ (67.5%), ‘responded with understanding and empathy’ (70%), ‘the facts and concepts were presented in a logical order’ (62.5%), ‘maintained control and direction of the orientation’ (85%). Refer to Table 4 for details.

Part 4 — Completion of the orientation

With respect to behaviours related to the completion of the orientation, analysis for Scenario 1 showed that 100% of the CPs did not exhibit the behaviours assessed in four of the items (see Table 5). In contrast, for Scenario 2, the behaviour in only one item was not observed in 100% of the CPs, specifically, ‘helped the patient (or agent) to plan the next steps and follow-up of the pharmacotherapy’. Further, in Scenario 2, it was observed that the CPs exhibited the behaviours assessed in some of the items to a satisfactorily or excellent level. These items were, ‘resumed, recognizing, and/or emphasizing the key points of information’ (47.5%), ‘provided an opportunity for questions or concerns’ (7.5%), and ‘assessed the patient’s (or agent’s) understanding through feedback’ (2.5%) (Table 5).

Finally, the difference between the performances of the CPs in both the scenarios in the present study was not statistically significant for any of the items analysed.

DISCUSSION

The study showed that the CPs lacked some clinical and communication skills. The scope of the information they provided to the SP focused on pharmacotherapy characteristics, instead of assessing the patient's complaint first, which further proves the CPs' poor performance regarding clinical assessment of the complaint and interpersonal communication.²⁴ Other studies that used the SP method in community pharmacies, have also demonstrated 'insufficient questioning' as a problem associated with non-prescription medicine consultations.^{13,14,17}

The present study confirms the feminization of the pharmacy profession in Brazil, corroborating the international trend in this phenomenon.²⁵⁻²⁹ Moreover, a study conducted in Aracaju, in 2010; with SPs who had headache and childhood diarrhoea also revealed that majority of the CPs were women.¹⁷ In this context, as the healthcare profession is aimed at providing care, which involves helping people in disease prevention, promotion, protection, and recovery of health, females may be more attuned to the practice of care.

A pharmacist requires adequate time for gathering clinically relevant information and evaluating the patient's needs, in order to recommend a non-prescription medicine. The literature advocates that pharmacists should designate at least 3 minutes per patient.³⁰ However, the amount of time the pharmacist spent in the current study was about half the recommended duration. In a similar study,¹⁷ the CPs spent a similar amount of time with the patient as in the present study. However, a study conducted in Slovenia presented different findings wherein the duration of consultation was 52.4 to 65.3 seconds.¹⁵ One of the reasons that may explain these findings is the lack of emphasis on health communication in the academic disciplines. This deficiency leads the students to believe that Pharmacy is a profession where they will not communicate with patients or their guardians.^{31,32}

We acknowledge that some pharmacists in the study provided some good advice to the SPs. For example, most of pharmacists referred the pregnant SP to a physician, a behaviour which was in keeping with the guidelines on expected outcomes provided by the expert panel in the present study. However, there were individual differences in the non-pharmacological therapies suggested by the CPs (ginger lozenge for the cough, and warm moist compresses for the pain) Further, the results showed that the standard of healthcare provided by the CPs was generally low, especially regarding the assessment of the characteristics of the presented complaint

(symptoms, time of onset of the complaint, associated symptoms, etc.). This could have hampered their recommendations for palliative treatments and/or referral to the doctor for careful evaluation of the complaint. Thus, it is important that community pharmacies improve the quality of their consultations in areas such as, pregnancy, particularly with regard to the in-depth elicitation of symptoms and details of the patients' situation.³³

Similarly, in Scenario 2, the CPs failed to investigate the complaint with which the SP approached them.²⁴ Such information would help them confirm their suspected diagnosis (type of complaint) and steer the decision making to meet the principles of pharmaceutical practice, i.e. to manage or detect health problems.³⁴ Thus, it is clear that pharmacists need to know the principles of patient counselling, health education, and clinical evaluation and be able to implement these competencies into their practice to ensure appropriate decision making.²⁴

It is important to note that one of CPs chose to prescribe a medicine for the treatment of sinusitis that is not allowed in Brazil. In Brazil, there is not a 'Pharmacy' category of medicines which only pharmacists can supply without a prescription. However, the recent resolution 586/2013³⁵ points out that the pharmacist can prescribe medicines which do not require prescription for dispensing. In this sense, the recommendation of this category of medicines would fit for the relief of symptoms reported by the SP as performed by CP.

In Scenario 2, the CPs only stated the name of the medication or mentioned the indication. Deschamps et al³⁶ examined the order in which information was presented to the patient by pharmacists. They highlighted that the order might be a reflection of the relative priority of what the pharmacists hope to accomplish with their consultation. An assertion like the one observed in the present study refers to the fact that pharmacists may meet the patients' health needs, but should also provide information about the medicines they use and about the health-related issues related to the medication prescribed.³⁷ Thus, it is important to mention the reason for the use of certain pharmacotherapy, as well as the substances present in the medicine. In contrast to guidelines provided by the expert panel in the present study, most of the pharmacists did not provide the information related to the MCBG tool's category of content of the orientation.

During patient counselling in a pharmacy, the pharmacist must observe, ask questions, discuss, and evaluate the patient in many ways, in order to obtain a comprehensive view of the guidance the patient requires. This is the first of the four principles suggested in the 'Optimization of Medicines' aimed to support patients to get the best outcomes from their use of medicines.³⁸

Patients go to a pharmacy to seek reassurance, for example, to confirm a suspicion about an ailment, to reaffirm that they are taking their medication correctly, or to confirm the need to visit a general practitioner.^{39,40}

Therefore, it is important for the CP to possess the expertise in identifying health risks or clinical conditions which need medical attention. However, the present study revealed that the CPs did not assess the patients' needs for information in a critical consciousness level,^{24,41} because their performance in the category 'introduction to the orientation' was low.

For example, the CPs did not introduce his/her self appropriately, explain the purpose of the orientation, assessed whether the patient had any other medical conditions, review the patient's understanding, any real concerns, and/or potential patient problems. These variables contribute to the recognition of the pharmacist as a health professional by the society and the understanding that the pharmacy is not a place that only sells medicine, but also provides treatment.⁴² These findings differ from those of Chui et al⁴⁰ in which the pharmacists were found to question patients about their medical and medication history. In addition, the pharmacists informed them about the possible side effects and ways of dealing with them. Moreover, pharmacists played a useful role in helping patients assess their medical needs and determine whether a physician's visit was necessary.^{3,43}

It is noteworthy that a high proportion of the CPs in the present study were found to obtain preliminary and pertinent information related to the drug request for Scenario 1. This may have occurred because the SP's pregnant status was overtly visible. Similarly, in Scenario 2, a considerable proportion of the CPs reviewed the SP's drug request before orientation, probably because the patient showed signals related to the ailment (facial pain on finger pressure and forward bending of the head). The pharmacists' focus on the product instead of the patient implies that the quality of pharmacist intervention was compromised,^{15,24} therefore acting as an impediment to choosing the best treatment option that guarantees the well-being of the patient. Moreover, the absence of instruments such as clinical protocols and algorithms to guide pharmaceutical intervention may also have compromised the performance of the CPs.²⁴ According to Mehuys et al⁴⁴, the use of such counselling protocol for patients efficiently assisted pharmacists in appropriate triage and selection of therapy.

With reference to the content of the orientation, a majority of the CPs merely provided basic information about the medication, which was brief and non-individualized. They did not provide much information about the safe and proper use of the non-prescription medicine and the need to seek the opinion of a medical consultant. In addition, the CPs exhibited low scores on providing information about the name and indication of the medicine, its dose and frequency, warnings regarding side effects, and helping the patient (or agent) to generate solutions to potential problems. They did not provide important pieces of information that would ensure the rational use of these medicines. As reported by Kasanaho et al⁴¹ the pharmacists use disconnected empirical knowledge, without analysing their actions in relation to such information. For example,

one CP prescribed a combination of an anti-inflammatory drug along with a muscle relaxant to treat the rib pain of the pregnant SP, without considering the risks to the health of the patient and the foetus. This combination of drugs contains substances that can cause uterine inertia and/or premature closure of the ductus arteriosus, particularly in the last three months of pregnancy,⁴⁵ which was the gestational age of the SP at the time of the study. Thus, these CPs need educational interventions⁴⁶ which impart basic clinical knowledge (disease management and therapeutic), patient counselling, and communication skills. The information need to be adapted to increase patient knowledge regarding proper and safe use of medication for the specific condition.^{15,17,36,41,43}

Effective communication with patients depends greatly on the degree of empathy demonstrated during the course of the conversation. It was rewarding to note that the CPs in the present study demonstrated a good level of empathy that could influence the use of open questions, and verbal and nonverbal behaviour. The pharmacist should use proper verbal and non-verbal communication skills during the counselling session,¹⁷ in order to establish a trustful relationship with the patient, and to ensure comprehension of the information provided by the CP. It is noteworthy that, the manipulation of the 'shopper' role (passive and active) in market studies of pharmacist-patient communication is strong evidence that the type of patient plays an important role in the pharmacist's content and style, and extent of communication.⁴⁷ However, contrary to these findings cited above, in the present study, there was no significant difference between the two scenarios for any of the items analysed.

Deschamps et al³⁶ pointed out that most of the time pharmacists did not explore the psychosocial concerns surrounding an illness. Probably the CPs who participated in the present study, were not aware of their responsibility as a healthcare professional, to promote, maintain and restore health, and prevent diseases.²⁴ To help achieve this, they need to interact with patients and facilitating positive experiences. Patients create positive or negative attitudes about the healthcare professionals with reference to their experience with the disease, treatment, and services provided.⁴² Considering these experiences is critical to meeting the patients' needs.^{48,49}

Thus, the role of the pharmacists should change from that of a paternalistic counsellor, towards a counsellor who supports the patient emotionally, and helps them to combine actions, knowledge, and feelings.^{36,41,47} In our study, we observed that, in both the scenarios, a high level of patient-pharmacist interactions leave the pharmacist in control, which does not provide an opportunity to the patient to express concerns or questions about their complaint. This indicates that the pharmacists may have been focused on prescribing the medicine alone. Moreover, the CPs may have believed that the patient does not contribute to the

process of providing effective pharmacist interventions. However, Deschamps et al³⁶ purported that allowing the patient to describe his/her situation and/or reason for receiving the current prescription is a good start to relationship building, and to patient-centred care.

The pharmacists' counselling regarding self-medication should include a logical line of questioning and two-way communication before the pharmacist recommends a product, and gives instructions and advice.⁴³ On the other hand, in both the scenarios, the CPs did not inquire with the SP about additional information that would enable them to establish a good therapeutic relationship, and to steer the care and share the decision-making between the patient and the pharmacist. Therefore, it may be concluded that the pharmacist's function of dispensing medication, while vital for patient care, may be a superficial practice in the profession. It does not utilize the CP's knowledge or skills sufficiently.⁵⁰ Such an assertion applies to this study, since it was evident that the communication model adopted did not focus on counselling patients. Thus, there is a need to adopt a problem-solving approach through which each patient's needs and level of understanding are taken into account.⁵¹ Further, the patients can use the expertise of pharmacists as a value added information resource on the use of non-prescription medicine and the management of minor ailments.^{43,52}

The 'Medication Counseling Behavior Guidelines' suggested by the USP⁵³, introduce practitioners to the principles of two-way communication and self-assessment of performance. As confirmed by Kasanaho et al⁴¹, this instrument proved to be a very practical tool to illustrate differences between the stages of counselling. The MCBG is also utilised in tutoring pharmacy students during their practical training period, teaching the principles of patient counselling.²³ An effective counselling process will lead to the expression of several queries by the patient. However, the CPs, especially in Scenario 1 showed very low scores for the items in the category on 'completion of orientation'. As the patient was a pregnant woman with a passive attitude, it was expected that the CPs would enable the clarification of any doubt about the ailment, as well as ensure that the patient had a complete understanding of the pharmacist intervention that had been proposed.

Perhaps, the clinical status of the SP in Scenario 1 justified the low scores of the CPs so as to avoid generating fear and apprehension regarding the medicine indication or practices for handling the complaint. These scores can also be justified by the lack of clinical knowledge (the exploration of the nature of the symptoms, and the possible causes and the implications of the symptoms) and communication skills. This was extensively explored by Berger et al³¹, who confirmed that communication apprehension is an impediment to effective practice. Thus, if pharmacy professionals and schools are serious about developing a patient-centred and service-oriented care, then communication courses must be a part of the pharmacy curriculum.²⁴ There is a

need for emphasis on both, improving skills, and reducing communication apprehension.^{31,32,54,55} In addition, simulation-based training improves students' knowledge, as well as clinical and communication skills.^{56,57}

The current study also had some limitations. Brazil is a large country, 47 % of South America, with widespread regional inequalities. The study included pharmacies from only one Brazilian state, and used convenience sampling. Therefore, the practice behaviour of pharmacists in the study may not be generalizable to other states. A random sample of all Brazilian pharmacies would be a more appropriate approach in order to improve the generalizability of the results. In addition, practice behaviour in response to the two clinical scenarios used in the study cannot be generalized to other clinical scenarios commonly presented in Brazilian community pharmacies. Further, this study did not provided feedback on the performance of CPs on simulated-patient assessment. Finally, the study did not measure behavioural change, or a lack thereof, over time.

In order to avoid bias the analysis was first done independently by the researchers, and then compared. In case of a scoring discrepancy, the video transcriptions were reviewed again and discussed until consensus was reached. It would be useful to repeat the study with a larger sample from different cities in Brazil, in order to observe the type of interventions, the questions to manager health problems, the performance in providing medicines and treatment during patient counselling.

Although a majority of the CPs offered consultation without being asked, serious deficiencies were found in some areas (clinical and communication skills). Important questions were asked by the CPs to aid decision-making (e.g. symptoms, characteristics); however, information regarding other important conditions or possible doubts about the complaint and the use of other medications to treat the symptom was not sufficiently explored.

The investigated CPs showed a lack of experience in applying theoretical knowledge in practice, and particularly in analysing the patients' needs (signs and symptoms), providing information about the medicines, and supporting patients to deal with doubts about the pharmacotherapy.

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Table 1. Simulated patient scenarios

Scenario 1: Patient presenting with dry cough (symptom-based request)

The patient is a woman aged 27 years, who is 6-months pregnant. She is complaining of dry cough accompanied by pain in the ribs. She states that she only used the medicines prescribed by the doctor for her pregnancy. She reported that the cough is stronger at bedtime. She had not consulted the doctor to investigate the problem. Hence, she had gone to the pharmacy, seeking medication for her symptoms.

Scenario 2: Patient presenting with facial pain (symptom-based request)

The patient is a woman aged 30 years, who works in an office that has air conditioning. She complains of facial pain (pointed to the maxillary sinus), a sore throat, and a stuffy and runny nose. She presents phlegm which is greenish in colour and thick. She had taken nasal drops (nafazolin) that she generally used when she experienced a runny nose. It improves for a while, after which the problem persists. She states that she had also used dipyrone the night before, for the face pain, but it did not work. She reports that when she bends to pick up something from the floor, her pain increases (pointing to the sinus). She reports, a little fever, but did not measure the temperature. She states that she had a flu that had not been resolved since a long time. She mentions that the facial pain appeared a month ago and points to the fact that it is getting cold. Therefore, she had gone to the pharmacy and requested something for the facial pain.

Table 2. Frequency distribution of the items in the introduction category of the MCBG tool during pharmacists' interactions with simulated patients in the two scenarios. Aracaju-SE/Brazil, 2012.

Items	Pregnant woman with dry cough (F/%)					Young woman with sinusitis (F/%)				
	1 ^a	2 ^b	3-5 ^c	6-7 ^d	8-10 ^e	1 ^a	2 ^b	3-5 ^c	6-7 ^d	8-10 ^e
At the beginning, leads the orientation, presenting and identifying who the patient is or the person responsible for him/her	20/50	7/17.5	9/ 22.5	4/10	0	23/57.5	3/7.5	12/30	2/5	0
Explain the purpose of the orientation	40/100	0	0	0	0	40/100	0	0	0	0
Review the patient's drug request before the orientation	25/62.5	0	8/20	7/ 17.5	0	5/12.5	5/12.5	12/30	15/37.5	3/7.5
Obtain preliminary and pertinent information related to the drug request	5/12.5	0	13/32.5	15/37.5	7/17.5	35/87.5	1/2.5	2/5	2/5	0
Warns the patient about the use of other drugs or substances, including non-prescription medicines, and herbal and alcoholic beverages, which could interact with the requested drug (increasing, decreasing or cancelling its action)	32/80	0	1/ 2.5	4/10	3/7.5	40/100	0	0	0	0
Determines whether the patient had other medical conditions which could influence the effects of the medication requested or the probability of an adverse reaction	29/72.5	0	6/15	2/5	3/7.5	32/80	0	4/10	3/7.5	1/2.5
Assesses the patient's understanding (or agent) of the requested pharmacotherapy	39/97.5	0	0	1/2.5	0	31/77.5	1/2.5	6/15	2/5	0
Assesses any real concerns and/or potential patient problems	37/92.5	0	1/2.5	1/2.5	1/2.5	35/87.5	0	0	5/12.5	0

^a Not done; ^bPoor; ^cUnsatisfactory; ^dSatisfactory; ^eExcellent.

Table 3. Frequency distribution of the items in the content category of the MCBG tool during pharmacists' interactions with simulated patients in the two scenarios. Aracaju-SE/Brazil, 2012.

Items	Pregnant woman with dry cough (F/%)					Young woman with sinusitis (F/%)				
	1 ^a	2 ^b	3-5 ^c	6-7 ^d	8-10 ^e	1 ^a	2 ^b	3-5 ^c	6-7 ^d	8-10 ^e
Discusses the name and indication of the medication	25/62.5	0	6/15	6/15	3/7.5	20/50	1/2.5	4/10	8/20	7/17.5
Explains the dosage regimen, including scheduling and duration of therapy when appropriate	16/40	0	3/7.5	1/2.5	3/7.5	26/65	0	6/15	6/15	2/5
Assists the patient (or agent) in developing a plan to incorporate the medication regimen into his/her daily routine	21/97.5	0	0	1/2.5	0	40/100	0	0	0	0
Explains how long it will take for the drug to show an effect	40/100	0	0	0	0	38/95	0	0	1/2.5	1/2.5
Discusses storage recommendations, ancillary instructions (e.g., shake well, refrigerate, etc.)	40/100	0	0	0	0	40/100	0	0	0	0
Emphasizes the benefits of completing the medication as directed	40/100	0	0	0	0	38/95	0	2/5	0	0
Warns the patient about the (significant) potential adverse effects of the medications	20/50	0	6/15	6/15	8/20	39/97.5	0	0	1/2.5	0
Discusses how to prevent or manage the side effects of the drug if they do occur	38/95	0	2/5	0	0	40/100	0	0	0	0
Discusses the precautions associated with the medication (activities to avoid, etc.)	38/95	0	0	2/5	0	40/100	0	0	0	0
Discusses significant drug-drug, drug-food, and drug-disease interactions	40/100	0	0	0	0	39/95	0	0	2/5	0
Explains in precise terms what to do if the patient misses a dose	40/100	0	0	0	0	40/100	0	0	0	0
Discusses with the patient potential problems in taking the medication as directed (e.g. cost, access, etc.)	37/92.5	0	3/7.5	0	0	40/100	0	0	0	0
Helps patient (or agent) generate solutions to potential problems	32/80	0	0	5/12.5	3/7.5	25/62.5	0	3/7.5	7/17.5	5/12.5
Provides detailed information about the pharmacotherapy	30/75	2/5	3/7.5	3/7.5	2/5	22/55	1/2.5	10/25	6/15	1/2.5

^a Not done; ^bPoor; ^cUnsatisfactory; ^dSatisfactory; ^eExcellent.

Table 4. Frequency distribution of process items during pharmacists interactions with simulated patients in the two scenarios. Aracaju-SE/Brazil, 2012.

Itens	Pregnant dry cough (n/%)					Young woman sinusitis (n/%)				
	1 ^a	2 ^b	3-5 ^c	6-7 ^d	8-10 ^e	1 ^a	2 ^b	3-5 ^c	6-7 ^d	8-10 ^e
Uses accessible language with the patient (or agent)	1/2.5	0	9/22.5	23/57.5	7/17.5	0	0	13/32.5	17/42.5	10/25
Uses the knowledge based on the literature, to support patient (or agent) orientation	22/55	4/10	2/5	4/10	8/20	3/7.5	3/7.5	7/17.5	11/27.5	16/40
Responds with understanding and empathy	0	8/20	12/30	14/35	6/15	0	5/12.5	7/17.5	21/52.5	7/17.5
Presents facts and concepts in a logical order	0	7/17.5	12/30	11/27.5	10/25	1/2.5	3/7.5	11/27.5	15/37.5	10/25
Maintains control and direction of the counselling session	0	3/7.5	3/7.5	24/60	10/25	1/2.5	2/5	3/7.5	23/57.5	11/27.5
Investigates additional information (e.g. lifestyle, beliefs)	40/100	0	0	0	0	40/100	0	0	0	0
Uses open-ended questions	9/22.5	9/22.5	10/25	9/22.5	3/7.5	5/12.5	7/17.5	18/45	9/22.5	1/2.5
In general, displays effective nonverbal behaviours	0	9/22.5	14/35	12/30	5/12.5	0	7/17.5	11/27.5	18/45	4/10
Appropriate eye contact	0	1/2.5	7/17.5	19/47.5	13/32.5	0	3/7.5	9/22.5	25/62.5	3/7.5
Voice is audible; tone and pace are good	0	0	3/7.5	14/35	23/57.5	0	2/5	18/45	12/30	8/20
Body language, postures, and gestures support the spoken message	0	7/17.5	9/22.5	11/27.5	13/32.5	0	5/12.5	10/25	20/50	5/12.5
Distance between the health care professional and patient is appropriate	0	2/5	11/27.5	24/60	3/7.5	0	2/5	4/10	27/67.5	7/17.5

^a Not done; ^bPoor; ^cUnsatisfactory; ^dSatisfactory; ^eExcellent.

Table 5. Frequency distribution of the items in the category on completion of orientation of the MCBG tool during pharmacists' interactions with simulated patients in the two scenarios. Aracaju-SE/Brazil, 2012.

Items	Pregnant woman with dry cough (F/%)					Young woman with sinusitis (F/%)				
	1 ^a	2 ^b	3-5 ^c	6-7 ^d	8-10 ^e	1 ^a	2 ^b	3-5 ^c	6-7 ^d	8-10 ^e
Assesses the patient's (or agent's) understanding through feedback	40/100	0	0	0	0	36/90	0	3/7.5	1/2.5	0
Resumes, recognizes, and/or emphasizes the key points of information	38/95	0	0	1/2.5	1/2.5	13/32.5	1/2.5	7/17.5	12/30	7/17.5
Provides an opportunity for questions or concerns	40/100	0	0	0	0	36/90	0	1/2.5	2/5	1/2.5
Helps the patient (or agent) to plan the next steps and follow-up of the pharmacotherapy	40/100	0	0	0	0	40/100	0	0	0	0

^a Not done; ^bPoor; ^cUnsatisfactory; ^dSatisfactory; ^eExcellent.

4.4 CAPÍTULO IV - DEVELOPMENT OF A DECISION SUPPORT SYSTEM FOR THE PRACTICE OF RESPONSIBLE SELF-MEDICATION

DEVELOPMENT OF A DECISION SUPPORT SYSTEM FOR THE PRACTICE OF RESPONSIBLE
SELF-MEDICATION

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SUMMARY STATEMENT

- The developed software can increase the security of community pharmacist in the management of self medication because it maintains patient records that allows pharmacist monitoring of patient progress, maintaining continuity of care and reporting patient to the GP.
- The software enables the preparation of a prescription in accordance with the current legislation on this pharmaceutical act. In the prescription will be present all the information about the proposed treatment and observations noted during pharmaceutical care.

BACKGROUND

Self-medication with non prescription medicine is common in many cultures, especially in developing countries.¹⁻⁴ This trend is justified due to low availability of health care services coupled with the lack of doctors and poverty. On the other hand, it is important to emphasize that self medication without the advice of a health professional, increases the risks of using expired medications and therapeutic indications mistakes made by relatives, friends and neighbors.^{5,6} Moreover, the repetition of prescriptions is another way of self-medication. In the United States, four in five Americans who visited the doctor left the office with at least one drug, surpassing the 3.5 billion annual prescriptions.⁷⁻⁹ These data lead to the annual expenditure of approximately U.S. \$ 234 billion with pharmacotherapy, and the impact of morbidity and mortality related to the drugs is around \$ 200 billion per year since 2001.¹⁰⁻¹²

According WHO, the increasing demand for health services in the last two decades justifies self-medication that when properly practiced contributes to relieve symptoms and reduce the demand for the public health system.¹³ In this scenario, responsible self medication is a practice accepted as an integral part of the health system and consists on the orientation of the patient by the community pharmacist in the treatment of minor illness with the use solely of non prescription medicines designed to treat minor symptoms.¹³ Thus, from the information provided by the community pharmacist is expected that the patient can use the most appropriate medicine, effective, safe and convenient.¹⁴⁻¹⁶

In this context, information properly managed by information systems can contribute to the solution of problems through aid in the process of diseases signs and symptoms identification and clinical decision making.¹⁷⁻¹⁹ Thus, health information can also be configured as the foundation of clinical decision process making based on evidence by community pharmacist, to choose the most suitable therapeutic goals and non prescription medicines for obtaining clinical outcomes that improve patient quality of life.²⁰⁻²²

In Medical and Pharmaceutical areas, management documentation has already been performed by information systems (software), which organize in a logical and efficient way the signs and symptoms of patients, allowing its analysis and suggesting diagnoses.^{23,24} However, no studies are cited about this kind of system toward community pharmacist, especially focused on the provision of responsible self-medication. With the expansion of the therapeutic arsenal is still evidenced the need of using information technology (record systems) that enables the community pharmacist access and use of accurate and recent information on behalf of the promotion, protection and recovery of health and prevention and treatment of diseases.

In this sense, the development of tools for guidance and decision support such as flowcharts and software, can assist the pharmacist in the identification process of minor illness and the choice of non prescription medicines, minimizing errors in dispensing.^{18, 25-27} Hence, it is necessary to invest in research that gives the necessary support for the development of software to facilitate the practice of responsible self-medication by the pharmacist. Therefore, this study aimed to develop a software capable to assist community pharmacist in clinical decision making on self-medication.

METHODS

The study was conducted from February 2012 to January 2014. The system development included the identification of minor illness commonly treated by community pharmacists²⁸ and presentation of simulations performed in community pharmacies using simulated patient methodology. Thus, it was possible to observe the competences of the pharmacist in the management of minor symptoms with non prescription medicines and identify the need to develop algorithms applied to the practice of responsible self-medication.²⁹

Thus was formed a group for the development of the tool. The members of the algorithm development group comprised 12 members including 7 clinical pharmacists with three years of experience in management of minor illness, 2 Production Engineering students, 2 professors (one of Clinical Pharmacy and other of developing softwares) and the Pharmacist researcher (CER). Five algorithm development meetings were held with this group from February 2012 to December 2013 (Figure 1). It is noteworthy that from October 2013 to February 2014 the project team (Production Engineering students, professors and the researcher) held meetings for finalization of the system in terms of its interface (fields needed to build the clinical and pharmacological history of the patient, pharmacist intervention proposal and preparation of pharmacist prescription) and crossing of information on signs and symptoms and current therapies. At the end of each meeting the researcher also formally recorded details of the meeting (e.g. numbers and identity of attendees, and purpose).

The purpose of the first meeting was conducted to address the question: “What are the key questions that need to be addressed by the algorithm for the management of upper respiratory tract minor illness (flu, cold, and sore throat) with non prescription medicines by community pharmacists?” The pharmacists with a range of clinical experience participated in a focus group discussion through brainstorming. During the meeting, the responses were discussed and ranked.

Pharmacists used clinical cases of the minor illness mentioned above, to determine the questions which should ensure proper diagnosis of the complaint and identifying situations of risk to patient health. The purpose of the second meeting was conducted to discuss the nonprescription medicines and lifestyle measures appropriate to treat these minor illness based on the scientific evidences. Then, drug therapy and lifestyle treatments for each case were listed; being appointed in what situations the patient should be referred to the doctor.

Subsequently, the collected data were translated into standard procedures represented as flowcharts and process maps that helped the project team in the organization of information that should be obtained from the patient questions. Thus, it was possible to ensure the inclusion of all relevant factors in the treatment of a complaint that lead pharmacist during the identification process of the complaint and consequently, the most appropriate decision making to improve the quality of life of the patient.

After the first drawing flowcharts and process maps the third meeting was held to optimize the outline of the computerized system in order to increase the efficiency of pharmacist intervention as to ensure the safety and well being of the patient. This was achieved through proper ordering of questions to patients regarding the frequency of occurrence of positive responses to signs and symptoms defined as a risk to patient health; it would be possible to forwarding decision or not a physician, as soon as possible by pharmacist.

When flowcharts are structured and optimized, the project team started the implementation phase (transcription of information updating the database of a computer system, crossing the pharmacological and non-pharmacological treatments for minor illness, test the software – 9^o - 25^o meeting) where all information obtained in the previous meetings was transcribed in the database of a computer system. The purpose of the fourth and the fifth meeting with the algorithm development group was to finalize the detailed content of the algorithms and test the software from a simulated patient who presented flu. Again, pharmacists tested the system version that was completed in December 2013. The final product was represented by a computerized system that allows pharmacists access through a simple and intuitive interface, so as to motivate their use by professionals who are not always accustomed to computational tools in their daily lives.

RESULTS

First meeting

The 12 members of the algorithm development group participated during the first meeting. The first stage of the focus group generated numerous issues many of which were combined following clarification amongst group members. After the discussion and first round ranking 13 items were selected (Table 1). The focus group pointed as main questions being carried those concerning to patient (age and sex), the general characteristic of symptoms (fever, congestion and nasal itching, runny nose, sneezing, cough, sore throat, headache, ear infections, facial pain, odor when sneezing, etc.), symptom onset, frequency, duration, location, presence of other diseases or warning signs that derive the patient to the doctor, medications used or in use and the result, allergy and triggering factors of the complaint or exacerbation of the condition. The final list of topics for inclusion in the algorithm indicated the exact questions to be addressed by the community pharmacist to manage properly the complaint.

Second meeting

The second meeting was attended by 10 group members. The discussions in the focus group indicated consensus among pharmacists as the substances in the list of Groups and Specified Therapeutic Indications of Brazilian Legislation as pharmacist interventions for the relief of complaint.³⁰ As lifestyle measures, these have involved cleaning the air conditioning or fan, taking adequate rest, increase increasing liquid intake, humidifying the air by using humidifiers, vaporizers, or hanging wet towels in the room, avoiding cigarette smoke or polluted environments, and using honey (if not diabetic) for the cough. If the patient had worsening of symptoms or had no response to treatment suggested by the pharmacist, the patient should be referred to the doctor.

Third meeting

This meeting was attended by 12 group members. The evaluation of the system by the group found that the questions relating to identification of risk situations to patient's health should follow the identification of the patient (age and sex). Thus, positive responses to the presence of comorbidities, warning signs (bleeding, lethargy, loss of consciousness, among others), negative results with the use of non prescription medicines less than 1 week (adverse reactions, worsening or aggravation of the complaint) are parameters to refer patients to the doctor.

Fourth meeting

This meeting was attended by 10 group members. The algorithm was tested based on a simulated patient with flu and sore throat with the aim to observe the order of the questions that would ensure a decision process effective, efficient and safe for the patient. It was noticed the need to differentiate between cases of infectious and non-infectious rhinitis and sinusitis from the rhinorrhea that occur with flu. Furthermore, assess the occurrence of sore throat frameworks that are derived from a viral infection. After these analyses, it was agreed that all group members would have a further opportunity to comment once the changes had been incorporated.

Fifth meeting

This meeting was attended by ten group members. The algorithm was presented, tested based on a simulated patient with flu, and agreed after the refinements as positive responses to the situations mentioned in the last meeting that determine referral to the doctor. Furthermore, the software could assist the pharmacist in finding situations of risk to patient health as the system incorporate medication and clinical data to support review of medication for appropriateness, and document pharmacist interventions. The software was also used to register and print pharmacist prescription.

System Development

The developed software has the function of collecting and storing information about the patient to ensure that the diagnosis is made in the most efficient and safest way possible. The software requires a user name and password to start, preventing it from being used by people who do not have clinical skills for managing minor symptoms with non-prescription drugs (Figure 2). The steps for using the system for the care of a patient are shown in Figure 3.

The first step in the process is to obtain the patient name. Through this information, the pharmacist can check if the patient is already a user of Pharmacy and hence if he has a clinical or drug therapy history registered. At a later stage, it is intended to have a single integrated database, so that the patient does not need to repeat your information in pharmacies that have the software. If the patient is not registered, the pharmacist asks the patient's age, given that this information determines whether the patient can be oriented by the pharmacist or whether it should be referred to a physician (this recommendation is made for patients with less than two years or over 60 years).

Next, the diagnosis process starts from the signs and symptoms reported by the patient. The software filter the diagnoses consistent with the set of signs and symptoms of the patient and then returns to the pharmacist a short list of possible minor ailments. From this list, the pharmacist should choose the most likely, based on their clinical judgment (Figure 4). It is noteworthy that the software is a support tool for pharmacist clinical decision support and the competence to perform the final diagnosis remains o pharmacist responsibility.

After diagnosis, the software displays a list of questions that should be made to the patient prior to treatment selection (Figure 5). The questions seek for information on chronic diseases, medications, allergies, among others. Depending on the response and provided data on the patient's history, the content and sequence of the questions will be personalized. Based on these answers, the software again will filter possible drug therapy and/ or lifestyle treatments, returning to the pharmacist only those who do not present a risk to patient health (Figure 6). This list of questions reduces the risk of irrational drug use, referring the patient to the doctor immediately, in cases which are not regulated by the care pharmacist. Although the final decisions of diagnosis and treatment to be recommended to the patient are pharmacist responsibility, the software takes care of filtering the possible options so that they are consistent with those presented symptoms and offer no risk to the patient regarding the choice of inappropriate treatments.

If the patient is already registered, the pharmacist may consult its history during dispensing. The screen shown in Figure 7 is available along that of Figure 4, when the pharmacist clicks the "HISTORY" button. In it are presented the symptoms and the proposed treatment (if any suggestion has been made) as referring patients to the doctor, medication use and/ or the adoption of lifestyle measures. Thus, the pharmacist may perform a comparative analysis of the current and previous clinical status of the patient. If the same complaint has been presented more than once in the Pharmacy, the pharmacist can view each of the visits by selecting the corresponding date. In summary, the software constructs the clinical and drug therapy history of the patient which gives safety to clinics and prescription pharmacist activities. With all of this information, it is up to pharmacists conduct their review and make the decision based on their clinical skills.

DISCUSSION

Information technology applied at Pharmacy enables, in addition to the management of medication use, the improvement of information management and clinical decision making.^{31,32} Hence, the application of this artifice in teaching students of Pharmacy and the training and support of the community pharmacist practice as to

the management of minor symptoms represent greater safety and efficiency in the provision of responsible self medication.

Community pharmacies are potential sites where the risks involved with self medication could be prevented, because community pharmacist have an overview of the prescription and non prescription medicines that patients are taking.³³⁻³⁶ Also, community pharmacists possess a high level of knowledge and are easily available to patients. This places them in a unique position to support self medication.³⁷⁻³⁹ In this sense, pharmacists recognized the need to educate patients about their role in self medication when managed in accordance with guidelines and algorithms.^{18,26}

Although most of these tools were developed to date have focused on Medical practice,⁴⁰ a limited number have been produced for the treatment of minor illness presented in community pharmacies that could be manager with non prescription medicines. The developed software can increase the security of community pharmacist in the management of self medication because it maintains patient records that allows pharmacist monitoring of patient progress, maintaining continuity of care and reporting patient to the GP. Also, the software could facilitate the reduction of misdiagnosis and the occurrence of drug related problems in the treatment of minor illness. Accurate record keeping was also suggested as a means of maintaining patient confidence.¹⁸ However, the need for clinical competence in assessing symptoms was noted.^{18,41}

According to Chaudhry et al.⁴² clinical decision support systems can improve adherence to guidelines and support efficiency by decreasing utilization of healthcare resources. In Medical area, is essential to achieve this purpose the availability of electronic health record that extract relevant information from the medical record in real time and present recommendations as soon as possible in medical consultation.⁴³⁻⁴⁵ In this sense, the present software allows storage of clinical and drug therapy patient information to identify situations of referral to the physician as well as contraindications for the use of certain non prescription medicines. This check would ensure that community pharmacist have considered all of the appropriate signs and symptoms needed for an accurate clinical decision support, and consequently, the drafting of pharmacist prescription.

You et al.⁴⁶ demonstrated in their study that 45.1% of the respondents agreed that community pharmacists could play a leading role in patient self medication of chronic diseases. In this sense, the software records the presence of other diseases in order to provide security in pharmacist decision-making process, particularly in identifying situations of risk to health and, therefore, refer the patient to the doctor. Since the 1990s the action of the community pharmacist next to the physician was responsible for the early diagnosis of diseases and consequently decreasing the suffering of the patient.⁴⁷⁻⁴⁹ General practitioners (GP) are generally

positive about the pharmacists' role in managing minor ailments but want patients to be referred if non prescription medicines failed or if the conditions were more serious, such as chest pain.⁵⁰⁻⁵² Findings confirmed that extending the role of community pharmacists should be more convenient for patients in terms of access to a health professional and longer opening hours and also should facilitate better use of GP time with complex patients.^{18,53}

It has been demonstrated that advice on self medication and counseling by community pharmacists has a measurable impact on health-related quality of life and that patients value the information that pharmacists provide.⁵⁴ So the software meets this perspective when enable the pharmacist to obtain information about the disease and the organization of the advice about self medication and the importance in adopting a healthy lifestyle. Pharmacists can play an important role in self medication by providing and interpreting information regarding appropriate health care and medication choices and they promote the rational use of drugs.⁵³

A recent systematic review revealed that studies supported the roles of pharmacists in improving the patient outcomes and health service utilization as well as delivering patient counseling and care regarding drug therapy and management of their disease condition.⁵⁵ The software enables the preparation of a prescription in accordance with the current legislation on this pharmaceutical act. In the prescription will be present all the information about the proposed treatment and observations noted during pharmaceutical care.

Programs on Pharmacy education have stimulated the use of virtual tools in teaching Pharmacy students with competence in providing independent, patient-centered, evidence-based pharmaceutical care.⁵⁶⁻⁵⁸ However, in Brazil and other develop countries the use of such tools in undergraduate Pharmacy is not cited. Thus, the developed software may fill gaps in the academic formation of pharmacists regarding clinical process decision making, development of knowledge and skills, patient assessment, and pharmacist prescription development.

On the other hand, it is important to emphasize that the software will help Pharmacy students and pharmacists only in the management of symptoms and treatments proposition. The selection of intervention will be linked to the clinical skills acquired and developed by students and pharmacists. Hands-on training experiences are necessary to move students into deeper levels of learning (i.e., learning to understand) by affording them practice at the application of the basic skills and knowledge necessary for provision of independent patient care as it relates to curricular material.⁵⁹

A weakness of the study is the lack of patient or public involvement in the design of the proposed software. Another weakness in study design was the limited numbers of clinical pharmacists who contribute. Those who contributed were interested in develop a software that would support community pharmacists in their

extended role in responsible self-medication. Piloting of the model will be undertaken with pharmacist students to teach minor illness management and community pharmacist. It must also be noted that this software, a model of care, will only be delivered by those pharmacist who feel competent to take responsibility for this extended role in minor illness management.

CONCLUSION

The software would allow improvement in the working conditions of community pharmacists, adding them greater scientific evidence that support its clinical decision-making on managing minor illness, and safe dispensing of medications during self medication. Also, the software may contribute to the identification of risk situations to patient health (potentially unsafe medications based on clinical history, clinical hazards, and adverse events experienced by patient) that require medical treatment. Furthermore, this tool may help fill some gaps in the training of pharmacists that could follow the proposed algorithm and undertake patient assessment, referral, non-invasive investigation and treatment. In later stages, the assessment of usability, functionality and reliability of the software will be made through its application in a sample of community pharmacists in order to visualize and quantify the clinical and economic impact on responsible self medication.

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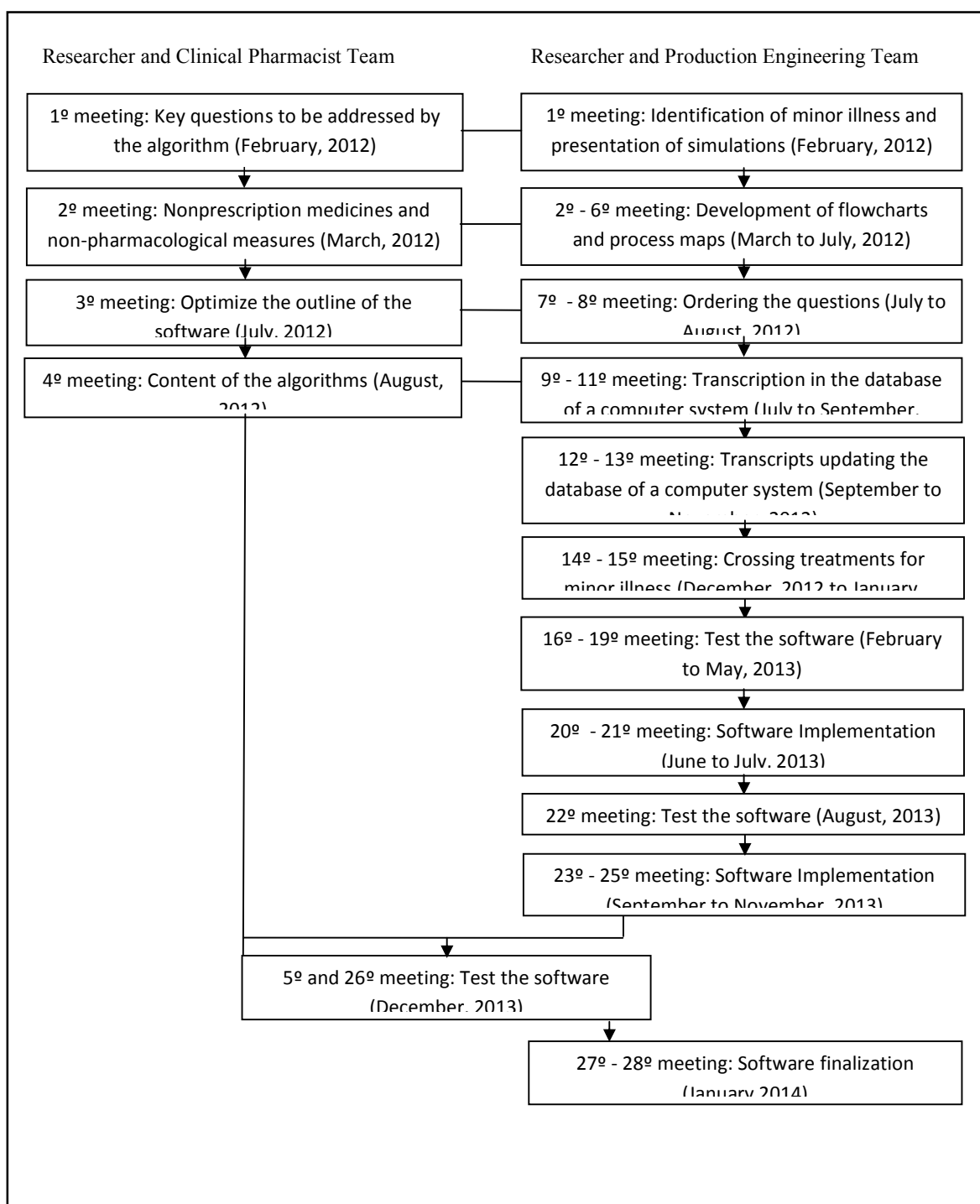


Figure 1. Framework Workflow. Aracaju-SE/ Brazil. 2012

Table 1. List of main issues selected from first round of the focus group. Aracaju-SE/ Brazil. 2012.

Order	Issue
1	Key information from patient (age, gender)
2	Contraindications (pregnancy and breast-feeding)
3	Characteristics of signals and symptoms (onset, frequency, intensity, duration, nature, location, presence of other symptoms, specific causes and aggravating or precipitating factors)
4	List of symptoms indicating other condition (facial pain, bad breath)
5	When to refer to a physician (presence of chronic diseases, treatment failure with non prescription medicines)
6	Medicines (continuous, prescribed, and OTC)
7	Others health problems (chronic diseases)
8	Allergies
9	Lifestyle counseling points (increasing liquid intake, humidifying the air, avoiding polluted environments or cigarette smoke, using honey (if not diabetic) for the cough)
10	Information on medicine proper use (nasal drops)
11	Appropriate treatment (complete information about the non prescription medicines and life style measures prescribed)
12	Pharmacist intervention (ensure patient consults clinician if treatment unsuccessful)
13	Time to evaluate the drug therapy or lifestyle outcome (after 48 hours of the pharmacist intervention)

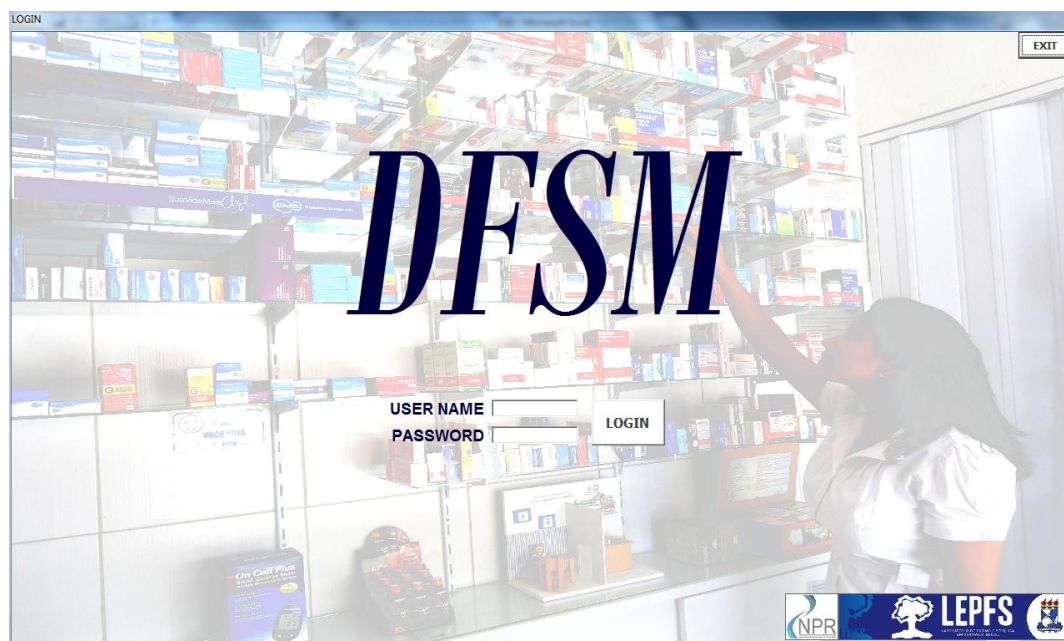


Figure 2. Screen access software. Aracaju-SE/ Brazil. 2014.

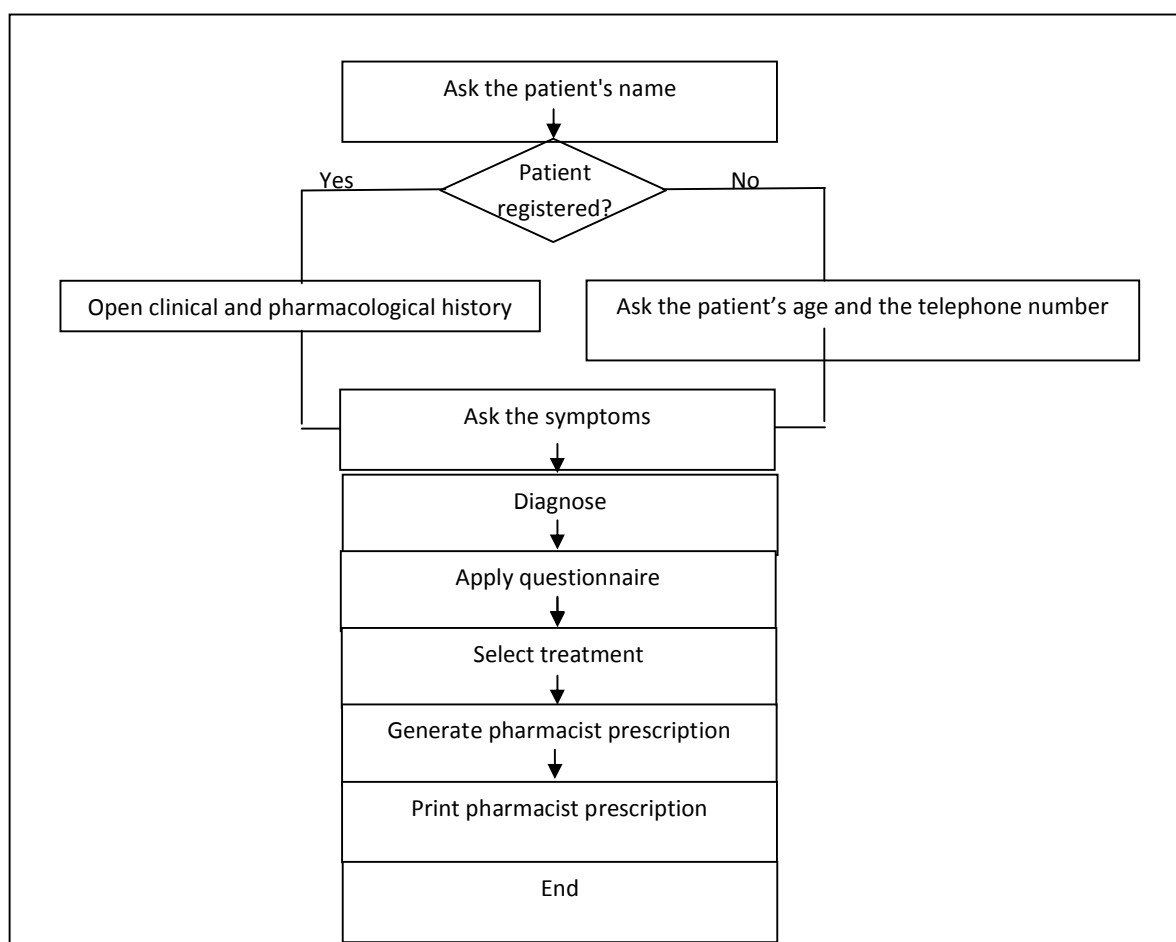


Figure 3. Flowchart of the process of patient care. Aracaju-SE/ Brazil. 2014.

MAIN SCREEN

NEW

EXIT

DATE

Name

JOÃO DA SILVA

Date of birth

23/12/1981

CPF or RG

354.658-88

GENDER

☒ M

☐ F

CONTACTS

Phone

((0XX) 1234-5678

Mobile

((0XX) 8765-4321

E-mail

joao@mail.com

SYMPTOMS

Headache

Sneezing

Nasal congestion

FIND

CLEAR

ASSUMPTIONS DIAGNOSTIC

FLU

COLD

RHINITIS

CHRONIC DISEASE

RENAL INSUFFICIENCY

ALLERGY

CLOPERASTINA

REFERRAL TO PHYSICIAN

Yes

RHINITIS

ENOUGH LIQUID INGESTION;
WORKPLACE HUMIDIFICATION

HISTORY

Figure 4: Experimental procedure with a simulated patient (homepage of the software). Aracaju/SE, Brazil, February to July, 2013.

The screenshot shows a web-based questionnaire titled "QUESTIONNAIRE" with a blue header bar. On the right side of the header are "RESET" and "RETURN" buttons. The main content area on the left contains several questions with radio button options:

- Pregnant or breastfeeding?**
☐ YES ☒ NO
- Do you have any chronic disease?**
☒ YES ☐ NO
- Do you have fever?**
☒ YES ☐ NO
- Below the fever question is an empty text input field.
- At the bottom of this section are the options ☐ YES ☐ NO.

In the center of the screen, a small dialog box is open with the text: "which was the temperature of your last measurement?". It features a numeric input field containing "39" followed by a degree symbol "°", and "OK" and "CANCEL" buttons at the bottom.

On the right side of the main interface is a purple-bordered box titled "Commentaries" containing a large empty white rectangular area for text entry.

Figure 5: Experimental procedure with a simulated patient (Checklist page). Aracaju/SE, Brazil, February to December, 2013.

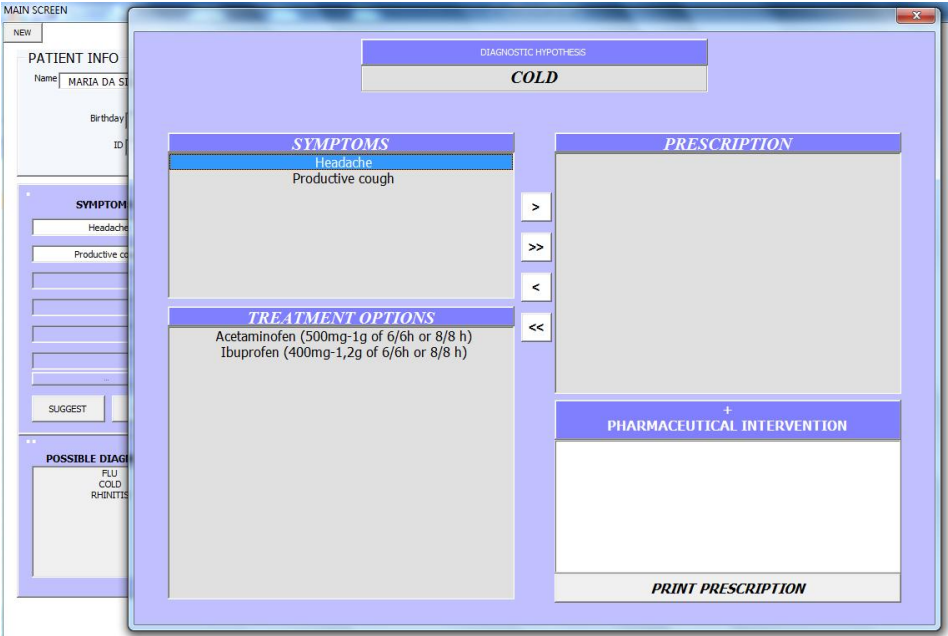


Figure 6: Experimental procedure with a simulated patient (Treatment page). Aracaju/SE, Brazil, January, 2014.

MAIN SCREEN

NEW

EXIT

PATIENT INFO

Name

JOÃO DA SILVA

Registered Patient

Birth day

23/12/1981

GENDER

☒ M
 ☐ F

ID

354.650-08

CONTACTS

Phone

(00X)1234-5678

Mobile

(00X)8765-4321

E-mail

joao@mail.com

Symptoms

SUGGEST

CLEAR

CHRONIC DISEASES

RENAL INSUFFICIENCY

ALLERGIES

CLOPERASTINA

POSSIBLE DIAGNOSTICS

HISTORY

JOÃO DA SILVA

PREVIOUS DIAGNOSTICS

01/10/2013

Symptoms

Headache

Snoring

Nasal congestion

PREGNANT OR BREASTFEEDING

No

REFERRED TO PHYSICIAN

Yes

DIAGNOSIS AND TREATMENT SUGGESTED

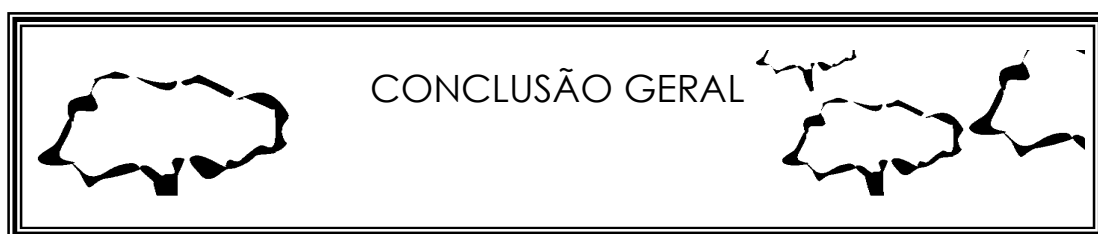
RHINITIS

PLENTY OF LIQUID INGESTION;

WORKPLACE HUMIDIFICATION

03/10/2013

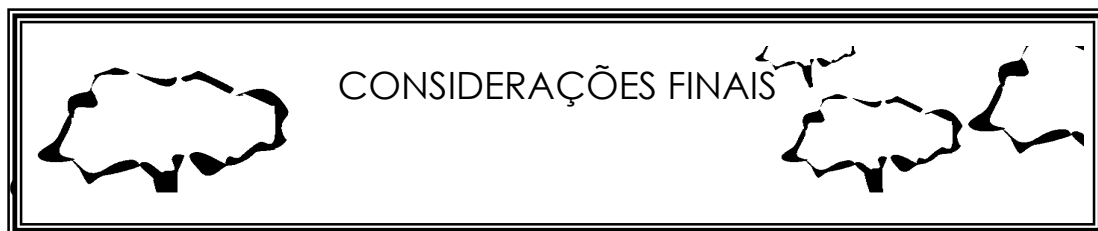
Figure 7: Experimental procedure with a simulated patient (History page). Aracaju/SE, Brazil, February to July, 2013 to January, 2014.



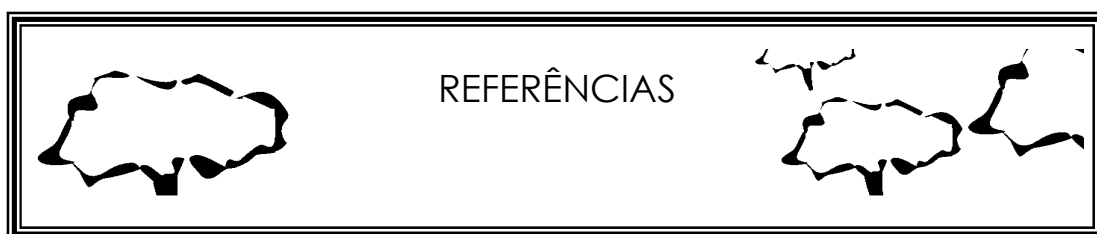
5. CONCLUSÃO GERAL

O conjunto dos resultados apresentados nesta Tese permitiu visualizar o perfil de manejo de sintomas menores com medicamentos não prescritos pelo farmacêutico comunitário e a necessidade de disponibilizar instrumentos como algoritmos para dá suporte a prática da automedicação responsável, além de ser um passo para a consolidação do novo paradigma farmacêutico que está emergindo no país. Além disso, os resultados específicos, demonstraram que:

1. A revisão sistemática revelou que ocorreram intervenções farmacêuticas escassas no manejo de sintomas menores com medicamentos não prescritos, as quais não eram avaliadas quanto ao seu impacto na melhora do sintoma menor apresentado. Contudo, os farmacêuticos utilizaram algoritmos e protocolos para avaliação das queixas e nos processos de tomada de decisão clínica quanto a escolha da terapia apropriada.
2. A carência de conhecimento farmacêutico sobre sintomas menores poderiam explicar as atitudes passivas dos farmacêuticos comunitários frente à automedicação.
3. As simulações demonstraram que o desempenho dos farmacêuticos comunitários no manejo de casos de sintomas menores com o uso de medicamentos não prescritos é insatisfatório, provavelmente por existirem lacunas na formação dos farmacêuticos (competências clínicas e de comunicação) que possivelmente comprometeram a avaliação das necessidades de saúde do paciente simulado e a provisão de informações sobre a doença e sobre a terapia selecionada.
4. O *software* poderá auxiliar os farmacêuticos comunitários na avaliação do paciente, pois o algoritmo implícito favorece a investigação não-invasiva, o estabelecimento do tratamento ou o encaminhamento ao médico. Além disso, o software poderá melhorar as condições de trabalho dos farmacêuticos, adicionando-lhes maior evidência científica e segurança no manejo de sintomas menores com medicamentos isentos de prescrição.



1. Ainda que os estudos quantitativos sejam utilizados para avaliar o perfil das intervenções farmacêuticas, futuras investigações deverão avaliar o impacto econômico, clínico e humanístico destas intervenções em sintomas menores em nível individual e do sistema de saúde.
2. A aplicação de algoritmos de tomada de decisão clínica no manejo de sintomas menores no âmbito da farmácia comunitária se configura como meio de instrumentalização rápida dos farmacêuticos no atendimento das necessidades de saúde da população. Posto isto, futuros estudos deverão propor o desenvolvimento e investigar a aplicabilidade destes instrumentos.
3. A tarefa das instituições de ensino superior na atualização das estruturas curriculares deverá atender as carências do sistema de saúde público e as necessidades de saúde prevalentes da população. Urge, então, acelerar o processo de mudança, inserindo disciplinas que permitam o desenvolvimento das competências clínicas (semiologia, terapêutica, farmacologia clínica) e de comunicação dos farmacêuticos.
4. O estabelecimento de programas de educação continuada constitui estratégia válida na formação dos farmacêuticos a fim de propiciar maior segurança na provisão da automedicação responsável. Medida esta que acompanha a recente resolução nº 586/2013, publicada pelo Conselho Federal de Farmácia que regulamenta a prescrição farmacêutica.
5. A aplicação de metodologias ativas no ensino do manejo de sintomas menores, conjuntamente a utilização de instrumentos validados que avaliam a qualidade da orientação farmacêutica prestada representam estratégias vindouras para capacitar os farmacêuticos na provisão da automedicação responsável.



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8.1 APÊNDICE A

TERMO DE CONSENTIMENTO LIVRE E ESCLARECIDO

Prezado(a) Farmacêutico(a)

Meu nome é **Chiara Erminia da Rocha** e sou **doutoranda do Programa de Pós-graduação em Ciências da Saúde da UFS** e no momento desenvolvo a pesquisa do meu projeto de doutorado sobre o tema **MANEJO DE SINTOMAS MENORES NA FARMÁCIA COMUNITÁRIA**, sob a orientação da Prof. Dr. Divaldo Pereira de Lyra Júnior. O objetivo principal deste trabalho é verificar as competências (conhecimento, habilidades e atitudes) do farmacêutico para o tratamento de sintomas menores em farmácias comunitárias de Aracaju (SE). Por este motivo convido você a participar da pesquisa.

Sua participação é muito importante para a realização do trabalho e espero que possa contribuir para o aperfeiçoamento e melhora da prática farmacêutica. Se você aceitar participar da pesquisa isto implica que você atenderá pacientes simulados no decorrer dos próximos três meses e será convidado (a) a participar de entrevistas coletivas junto com seus colegas farmacêuticos, o que nós chamamos de grupo focal. Estas entrevistas serão registradas com o auxílio de um gravador de áudio e vídeo.

Sua participação é voluntária e você tem todo o direito de não concordar em participar ou desistir em continuar na pesquisa a qualquer momento sem nenhum tipo de ônus. Planejamos todos os procedimentos da pesquisa com o cuidado minimizar danos ou desconfortos a você, no entanto, se você não se sentir à vontade, você não é obrigado a responder qualquer pergunta formulada durante a entrevista e poderá contatar a pesquisadora para retirar o seu consentimento quanto a participação da etapa de simulação.

Ressaltamos que os resultados da pesquisa destinam-se à finalidade acadêmica e será garantido o sigilo de qualquer tipo de informação que possa identificá-lo (a). Bem como, que o projeto já foi aprovado pelo Comitê de Ética em Pesquisa do Hospital Universitário da Universidade Federal de Sergipe sob protocolo nº CAAE – 0898.0000107-09, e que sua realização foi autorizada por esta Rede de Farmácias. Quaisquer dúvidas ou necessidade de esclarecimentos poderão ser dirimidas junto à pesquisadora Chiara Erminia da Rocha, cujos telefones são (79) 8826 7087 (TIM) e (79) 8848 7978 (OI).

Eu, _____, RG. _____, informo que fui devidamente esclarecido(a) e concordo em participar da referida pesquisa. Declaro ainda que recebi uma cópia do presente documento. Aracaju, ____/____/____

Assinatura

Nome do Pesquisador: Chiara Erminia da Rocha Endereço: Rua do Sol, nº 27, casa 11. Bairro Aeroporto. CEP: 49038-380 Telefone: (079) 8826 7087/ 8848 7978	Nome do Orientador: Divaldo P. de Lyra Júnior Endereço: Avenida Maria Pastora, nº 84, Bairro Farolândia. CEP: 49030-210 Telefone: (079) 21056844 / 9192-5577
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8.2 APÊNDICE B

PESQUISA SOBRE COMPETÊNCIAS FARMACÊUTICAS PARA O MANEJO DE SINTOMAS MENORES COM
MEDICAMENTOS ISENTOS DE PRESCRIÇÃO. ARACAJU, 2012

PARTE I – DADOS DO ENTREVISTADO

/ /

1. NOME DO ENTREVISTADO _____

2. ENDEREÇO DO TRABALHO _____

3. SEXO []

1. ☐ MASCULINO 2. ☐ FEMININO

4. DATA DE NASCIMENTO _____ []

PARTE II – INFORMAÇÕES DO ENTREVISTADO

5. HÁ QUANTO TEMPO O Sr. (Sra.) SE GRADUOU EM FARMÁCIA? _____ []

6. EM QUAL IES SE GRADUOU? _____ []

7. O Sr. (Sra.) FEZ ALGUM TIPO DE PÓS-GRADUAÇÃO? []

1. ☐ SIM 2. ☐ NÃO

8. SE SIM, QUAL O TIPO? _____

9. HÁ QUANTO TEMPO O Sr. (Sra.) TRABALHA EM FARMÁCIA COMUNITÁRIA? _____ []

10. O Sr. (Sra.) SABE O QUE É SINTOMA MENOR/DOENÇA AGUDA? []

1. ☐ SIM 2. ☐ NÃO 9. ☐ NÃO SABE

11. SE SIM, QUAL O CONCEITO? _____

12. SE SIM, O Sr. (Sra.) PODE CITAR UM EXEMPLO? _____

13. O Sr. (Sra.) DURANTE A GRADUAÇÃO TEVE ALGUMA DISCIPLINA NA ÁREA DE MANEJO DE SINTOMAS
MENORES/DOENÇA AGUDA? []

1. ☐ SIM 2. ☐ NÃO 9. ☐ NÃO SABE

14. SE SIM, QUAL O NOME DA DISCIPLINA? _____

15. O Sr. (Sra.) CONHECE ALGUMA LEI QUE PERMITE AO FARMACÊUTICO INDICAR MIPS? []

1. ☐ SIM

2. ☐ NÃO

9. ☐ NÃO SABE

16. SE SIM, O Sr. (Sra.) PODERIA CITAR A LEI? _____

17. EXISTE ALGUM TIPO DE FONTE DE INFORMAÇÃO SOBRE MEDICAMENTOS E DOENÇAS DISPONÍVEL NA FARMÁCIA? []

1. ☐ SIM

2. ☐ NÃO

18. SE SIM, QUAL? _____

19. O QUE O Sr. (Sra.) FAZ QUANDO UM CONSUMIDOR ESTÁ SE AUTOMEDICANDO E PEDE A SUA OPINIÃO? _____



9.1 ANEXO A***African Journal of Pharmacy and Pharmacology***

Dear Prof Rocha Chiara

Your manuscript has been received by our Editorial Office and we have commenced the processing of the manuscript. You will be able to monitor the progress of your manuscript by using our manuscript management portal on www.ms.academicjournals.org. Kindly login as an author. Thank you once again for submitting your manuscript to our journal.

Date 09-Oct-2013

Manuscript Number AJPP/08.10.13/3913

Manuscript Title PHARMACIST INTERVENTIONS IN MANAGING MINOR ILLNESSES WITH NON-PRESCRIPTION MEDICINES: A SYSTEMATIC REVIEW

Current Status Acknowledgement

9.2 ANEXO B

Instructions for Authors

The **African Journal of Pharmacy and Pharmacology (AJPP)** is an open access journal that provides rapid publication (weekly) of articles in all areas of Pharmaceutical Science such as Pharmaceutical Microbiology, Pharmaceutical Raw Material Science, Formulations, Molecular modeling, Health sector Reforms, Drug Delivery, Pharmacokinetics and Pharmacodynamics, Pharmacognosy, Social and Administrative Pharmacy, Pharmaceutics and Pharmaceutical Microbiology, Herbal Medicines research, Pharmaceutical Raw Materials development/utilization, Novel drug delivery systems, Polymer/Cosmetic Science, Food/Drug Interaction, Herbal drugs evaluation, Physical Pharmaceutics, Medication management, Cosmetic Science, pharmaceuticals, pharmacology, pharmaceutical research etc. The Journal welcomes the submission of manuscripts that meet the general criteria of significance and scientific excellence.

Electronic submission of manuscripts is strongly encouraged, provided that the text, tables, and figures are included in a single Microsoft Word file (preferably in Arial font).

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Article Types

Three types of manuscripts may be submitted:

Regular articles: These should describe new and carefully confirmed findings, and experimental procedures should be given in sufficient detail for others to verify the work. The length of a full paper should be the minimum required to describe and interpret the work clearly.

Short Communications: A Short Communication is suitable for recording the results of complete small investigations or giving details of new models or hypotheses, innovative methods, techniques or apparatus. The style of main sections need not conform to that of full-length papers. Short communications are 2 to 4 printed pages (about 6 to 12 manuscript pages) in length.

Reviews: Submissions of reviews and perspectives covering topics of current interest are welcome and encouraged. Reviews should be concise and no longer than 4-6 printed pages (**about 12 to 18 manuscript pages**). Reviews are also peer-reviewed.

Review

Process

All manuscripts are reviewed by an editor and members of the Editorial Board or qualified outside reviewers. Authors cannot nominate reviewers. Only reviewers randomly selected from our database with specialization in the subject area will be contacted to evaluate the manuscripts. The process will be blind review.

Decisions will be made as rapidly as possible, and the journal strives to return reviewers' comments to authors as soon as possible. The editorial board will re-review manuscripts that are accepted pending revision. It is the goal of the AJPP to publish manuscripts shortly after submission.

Regular

articles

All portions of the manuscript must be typed double-spaced and all pages numbered starting from the title page.

The Title should be a brief phrase describing the contents of the paper. The Title Page should include the authors' full names and affiliations, the name of the corresponding author along with phone, fax and E-mail information. Present addresses of authors

should appear as a footnote.

The Abstract should be informative and completely self-explanatory, briefly present the topic, state the scope of the experiments, indicate significant data, and point out major findings and conclusions. The Abstract should be 100 to 200 words in length.. Complete sentences, active verbs, and the third person should be used, and the abstract should be written in the past tense. Standard nomenclature should be used and abbreviations should be avoided. No literature should be cited. Following the abstract, about 3 to 10 key words that will provide indexing references should be listed.

A list of non-standard Abbreviations should be added. In general, non-standard abbreviations should be used only when the full term is very long and used often. Each abbreviation should be spelled out and introduced in parentheses the first time it is used in the text. Only recommended SI units should be used. Authors should use the solidus presentation (mg/ml). Standard abbreviations (such as ATP and DNA) need not be defined.

The Introduction should provide a clear statement of the problem, the relevant literature on the subject, and the proposed approach or solution. It should be understandable to colleagues from a broad range of scientific disciplines. Materials and methods should be complete enough to allow experiments to be reproduced. However, only truly new procedures should be described in detail; previously published procedures should be cited, and important modifications of published procedures should be mentioned briefly. Capitalize trade names and include the manufacturer's name and address. Subheadings should be used. Methods in general use need not be described in detail.

Results should be presented with clarity and precision. The results should be written in the past tense when describing findings in the authors' experiments. Previously published findings should be written in the present tense. Results should be explained, but largely without referring to the literature. Discussion, speculation and detailed interpretation of data should not be included in the Results but should be put into the Discussion section. The Discussion should interpret the findings in view of the results obtained in this and in past studies on this topic. State the conclusions in a few sentences at the end of the paper. The Results and Discussion sections can include subheadings, and when appropriate, both sections can be combined. The Acknowledgments of people, grants, funds, etc should be brief. Tables should be kept to a minimum and be designed to be as simple as possible. Tables are to be typed double-spaced throughout, including headings and footnotes. Each table should be on a separate page, numbered consecutively in Arabic numerals and supplied with a heading and a legend. Tables should be self-explanatory without reference to the text. The details of the methods used in the experiments should preferably be described in the legend instead of in the text. The same data should not be presented in both table and graph form or repeated in the text.

Figure legends should be typed in numerical order on a separate sheet. Graphics should be prepared using applications capable of generating high resolution GIF, TIFF, JPEG or Powerpoint before pasting in the Microsoft Word manuscript file. Tables should be prepared in Microsoft Word. Use Arabic numerals to designate figures and upper case letters for their parts (Figure 1). Begin each legend with a title and include sufficient description so that the figure is understandable without reading the text of the manuscript. Information given in legends should not be repeated in the text. References: In the text, a reference identified by means of an author's name should be followed by the date of the reference in parentheses. When there are more than two authors, only the first author's name should be mentioned, followed by 'et al'. In the event that an author cited has had two or more works published during the same year, the reference, both in the text and in the reference list, should be identified by a lower case letter like 'a' and 'b' after the date to distinguish the works.

Examples:

Cole (2000), Steddy et al. (2003), (Kelebeni, 1983), (Bane and Jake, 1992), (Chege, 1998; Cohen, 1987a,b; Tristan, 1993,1995), (Kumasi et al., 2001) References should be listed at the end of the paper in alphabetical order. Articles in preparation or articles submitted for publication, unpublished observations, personal communications, etc. should not be included in the reference list but should only be mentioned in the article text (e.g., A. Kingori, University of Nairobi, Kenya, personal communication). Journal names are abbreviated according to Chemical Abstracts. Authors are fully responsible for the accuracy of the references.

Ansell J, Hirsh J, Poller L (2004). The pharmacology and management of the vitamin K antagonists: the Seventh ACCP Conference on Antithrombotic and Thrombolytic Therapy. 126:204-233

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Short

Communications

Short Communications are limited to a maximum of two figures and one table. They should present a complete study that is more limited in scope than is found in full-length papers. The items of manuscript preparation listed above apply to Short Communications with the following differences: (1) Abstracts are limited to 100 words; (2) instead of a separate Materials and Methods section, experimental procedures may be incorporated into Figure Legends and Table footnotes; (3) Results and Discussion should be combined into a single section.

Proofs and Reprints: Electronic proofs will be sent (e-mail attachment) to the corresponding author as a PDF file. Page proofs are considered to be the final version of the manuscript. With the exception of typographical or minor clerical errors, no changes will be made in the manuscript at the proof stage. Because AJPP will be published freely online to attract a wide audience), authors will have free electronic access to the full text (in both HTML and PDF) of the article. Authors can freely download the PDF file from which they can print unlimited copies of their articles.

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9.3 ANEXO C -

March 10, 2014

Dear Dr. Chiara Erminia da Rocha,

I am pleased to inform you that your manuscript titled as "WHAT DO BRAZILIAN COMMUNITY PHARMACISTS KNOW ABOUT SELF-MEDICATION FOR MINOR ILLNESSES? A PILOT STUDY IN THE NORTHEAST OF BRAZIL." (Manuscript Number: JAPS-2014-03-065 was accepted for publication in the Journal of Applied Pharmaceutical Science. You are required to submit article processing charges Rs. 1500/- INR (Indian Authors) or USD 75 (foreign authors) within next three days of receiving this mail through Banking/Paypal. Payment details are as follows;

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I would like to remind that you could send your future manuscripts to Journal of Applied Pharmaceutical Science.

Sincerely yours,

Paras Sharma

Associate Editor

Journal of Applied Pharmaceutical Science

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9.4 ANEXO D

Assunto:	A manuscript number has been assigned to your SIH submission
De:	Simulation in Healthcare (journal@ssih.org)
Para:	chiara.ermania@yahoo.com.br;
Data:	Sexta-feira, 28 de Março de 2014 22:20

Mar 28, 2014

Dear Mrs. Rocha,

Your submission entitled "ASSESSMENT OF THE COUNSELLING PRACTICES OF COMMUNITY PHARMACISTS WITH SIMULATED PATIENTS WITH MINOR ILLNESS - A PILOT STUDY" has been assigned the following manuscript number: SIH-D-14-00060.

You will be able to check on the progress of your paper by logging on to Editorial Manager as an author.


<http://sih.edmgr.com/>

Thank you for submitting your work to Simulation in Healthcare.

Kind Regards,

Karl W. Durst
Managing Editor
Simulation in Healthcare

9.6 ANEXO E

Simulation in Healthcare Online Submission and Review System	 Author Resources Instructions for Authors (this page) Copyright Transfer and Financial Disclosure Form (PDF) Reprint Ordering Permissions Requests Reprints
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Online ISSN:	1559-713X
Frequency:	6 issues / year
Ranking:	42 out of 82 in Health Care Sciences & Services
Impact Factor:	1.635

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I. GENERAL EDITORIAL, LEGAL AND ETHICAL ISSUES

A. Authorship

Each manuscript must have a "Corresponding Author." However, all authors must have participated in the design, execution, and/or analysis of the work presented, and attest to the accuracy and validity of the contents. All persons or organizations involved in the work must be listed as authors or acknowledged. Manuscripts are received with the understanding that they have been written by the authors; ghostwritten papers are unacceptable.

B. Duplicate, Prior or Divided Publication

Submitted manuscripts must not have been published elsewhere, in whole or in part, on paper or electronically. This includes personal, departmental, educational or other Web sites. This does not apply to abstracts of scientific meetings, or to lecture handouts. *Simulation in Healthcare* discourages authors from dividing the results of a single study into multiple papers. Do not submit several small manuscripts; a single comprehensive paper is preferable. If the authors believe that subdivision is appropriate, or if multiple articles may result from the same study, contact the Editor-in-Chief. The Editor-in-Chief must be notified if another manuscript derived from the same experiment has been published previously, or has been submitted to another journal.

C. Human Studies

Human experimentation must conform to ethical standards. For any data gathering effort on human subjects (including learners or teachers in educational activities), when an ethical review committee (known commonly in the United States as an Institutional Review Board -- IRB) exists with sufficient knowledge and jurisdiction to judge the ethical stratus of a research project it should be consulted. Any study must have the approval of the ethical review committee or equivalent body, or adhere to appropriate local, regional, and national standards and procedures. While some research approaches in simulation may qualify for "exempt" status and/or may not require written informed consent by subjects, in general (certainly in the United States) the ethical review committee must review the protocol and approve the exempt status; the investigator cannot make this decision. In some regions the policy may be different, but it will be the authors' responsibility to document that they have complied with all local, regional, and national standards, laws, and regulations.

A statement concerning ethical review committee (or equivalent body) approval and consent procedures MUST appear in the Methods section of the manuscript. If there is no suitable ethical committee to submit the research proposal to, the corresponding author must document that this is the case and include that in the manuscript submission. The manuscript should then provide information as to the ethical care taken in the research project. In such a case researchers should describe in the manuscript, at a minimum, the informed consent procedure (if any), the means to ensure completely voluntary participation in the research, procedures for the briefing of the participants, maximum avoidance of deception unless the experiment is followed by disclosure of the truth, utmost prevention of any physical or psychological harm to the participant, and steps taken to ensure confidentiality of data, and anonymity for participants in the manuscript.

Authors may be questioned about the details of human subjects protocols, approvals, procedures, consent forms or the consent process. On occasion, the Editor-in-Chief may request from the author a copy of the approved application to an ethical review committee (or equivalent body). Note that lack of appropriate approvals, lack of appropriate consent, or inadequate documentation will be grounds for rejection. Note that approval by an ethical review committee (or equivalent body), or conformance to local, regional, and national

standards does not guarantee acceptability by the Journal whose standards may be higher than those of the ethical review committee; the final decision will be made by the Editor-in-Chief.

D. **Animal**

Studies

Experimental work on animals must conform to the guidelines laid out in the Guide for the Care and Use of Laboratory Animals, which is available from the National Academy of Science; a text-only version is available at <http://www.nap.edu/readingroom/books/labrats/>. Adherence to all relevant regulations and/or approval of the appropriate institutional Animal Care Committee or governmental licensure of the investigator and/or laboratory must be obtained. A statement concerning such approval must be included at the beginning of the Methods section. Authors may be questioned regarding the use of anesthetics, muscle relaxants, and postoperative analgesics. On occasion, the Editor-in-Chief may request a copy of the approved Animal Care Committee application from the author. Major issues are a) the postoperative use of analgesics following surgical procedures, and b) the use of neuromuscular blocking drugs, particularly in minimally sedated animals. Local committee approval does not guarantee acceptability; the final decision will be made by the Editor-in-Chief.

E. **Conflicts of Interest and Sponsorship**

The Editors of *Simulation in Healthcare* are concerned about any real or perceived conflicts of interest. Authors must complete a detailed online form (<http://edmqr.ovid.com/sih/accounts/copyrightTransfer.pdf>) asking about relationships pertaining to both the work under consideration and activities outside the submitted work. Instructions on completing this form are in the following section.

In addition to completing and electronically signing the Copyright Transfer and Financial Disclosure Online Form, authors should include in the manuscript -- after the Discussion but before the References -- a separate paragraph (titled Financial Disclosure Summary) which clearly summarizes the financial disclosure/conflict of interest(s) that are filed on the Disclosure form in a manner that can be understood by readers of the Journal. The Editorial Office will copyedit the statement for compliance with Journal standards. This paragraph will accompany the paper (typically as a footnote) should it be published. The paragraph should convey enough information as to the nature and magnitude of any potentially conflicting interests to allow the reader to make a judgment as to whether such relationship could have had any impact on the conduct or results of the work described.

INSTRUCTIONS FOR COMPLETING THE FINANCIAL DISCLOSURE SECTION OF THE COPYRIGHT TRANSFER AND FINANCIAL DISCLOSURE FORM:

The Work Under Consideration for Publication

This section asks for information about the work that you have submitted for publication. The time frame for this reporting is that of the work itself, from the initial conception and planning to the present. The requested information is about resources that you received, either directly or indirectly (via your institution), to enable you to complete the work. Checking "No" means that you did the work without receiving any financial support from any third party -- that is, the work was supported by funds from the same institution that pays your salary and that institution did not receive third-party funds with which to pay you. If you or your institution received funds from a third party to support the work, such as a government granting agency, charitable foundation or commercial sponsor, check "Yes". Then complete the appropriate boxes to indicate the type of support and whether the payment went to you, or to your institution, or both.

Relevant Financial Activities Outside the Submitted Work

This section asks about your financial relationships with entities in the bio-medical and simulation arena that could be perceived to influence, or that give the appearance of potentially influencing, what you wrote in the submitted work. You should disclose interactions with ANY entity that could be considered broadly relevant to the work. For example, if your article is about testing a mannequin-based simulator in emergency medicine, you should report ALL associations with entities pursuing simulation strategies in general, not just in the area of mannequin-based simulation or emergency medicine. *If there is any question, it is usually better to disclose a relationship than not to do so.*

Report all sources of revenue paid (or promised to be paid) directly to you or your institution on your behalf over the 36 months prior to submission of the work. This should include all monies from sources with relevance to the submitted work, not just monies from the entity that sponsored the research. Please note that your interactions with the work's sponsor that are outside the submitted work should also be listed here. For grants you have received for work outside the submitted work, you should disclose support ONLY from entities that could be perceived to be affected financially by the published work, such as drug or device companies, simulation centers, or foundations primarily supported by entities that could be perceived to have a financial stake in the outcome. Public funding sources, such as government agencies, charitable foundations or academic institutions need not be disclosed. For example, if a government agency sponsored a study in which you have been involved and a simulator or supplies for that device were provided to you by a company, you need only list the company.

Other

Relationships

Use this section to report other relationships or activities that readers could perceive to have influenced, or that give the appearance of potentially influencing, what you wrote in the submitted work. These are not limited to financial relationships or activities.

F. **Compliance with NIH and Other Research Funding Agency Accessibility Requirements**

A number of research funding agencies now require or request authors to submit the post-print (the article after peer review and acceptance but not the final published article) to a repository that is accessible online by all without charge. As a service to *Simulation in Healthcare's* authors, Lippincott Williams & Wilkins will identify to the National Library of

Medicine (NLM) articles that require deposit and will transmit the post-print of an article based on research funded in whole or in part by the National Institutes of Health, Wellcome Trust, Howard Hughes Medical Institute, or other funding agencies to PubMed Central. The Copyright Transfer Agreement provides the mechanism.

G. **Study** **Design** **Issues:**

Clinical Trials and Surveys

1. Clinical Trials: Authors of clinical trials involving the treatment of patients (regardless of size) should consult the guidelines published by the CONSORT group [Moher D, et al for the CONSORT Group: The CONSORT statement: Revised recommendations for improving the quality of reports of parallel-group randomized trials. *JAMA* 2001; 285:1987-91 at <http://www.consort-statement.org>]
2. Surveys: *Simulation in Healthcare* welcomes papers based on well-done surveys. However, the quality of the survey methodology is often a factor in the Editor-in-Chief's decision. Interested authors should review the material contained in the following article: Burmeister LF. Principles of Successful Sample Surveys, *Anesthesiology* 2003; 99: 1251-1252.

II. TYPES OF PAPERS

Several types of papers are published. If in doubt regarding the suitability of a submission, please [contact the Editorial Office](#).

- A. **Empirical Investigations**. Empirical Investigations present results of original empirical research. Articles range in length from 1,500 to 4,000 words. Abbreviated Titles, Summary Statements, and Abstracts are required (see the section on Manuscript Preparation below).
- B. **Technical Reports**. Technical reports present technical information regarding simulation techniques or technologies, to assist others in the simulation community to replicate novel advances in the field. These brief articles range from 1,000 to 3,000 words. Abbreviated Titles, and Abstracts are required (see the section on Manuscript Preparation below).
- C. **Concepts and Commentaries**. These are brief reviews and commentary (2,000 to 3,000 words) focused on specific topics of relevance to the simulation community. Do NOT submit Abstracts. Abbreviated Titles and Summary Statements are required (see the section on Manuscript Preparation below).
- D. **Case Reports and Simulation Scenarios**. Case Reports and Simulation Scenarios draw attention to important clinical situations, new treatments or complications, and how they can be represented or replicated in simulations. They range in length from 500 to 1,500 words. Do not submit Abbreviated Titles, Summary Statements, and Abstracts (see the section on Manuscript Preparation below). Simulation case scenarios may follow any format that fully describes the case and its simulation implementation. Authors are encouraged (but not required) to use the template format promulgated by the Duke University Simulation Center, available at http://anesthesiology.duke.edu/?page_id=824799. Some elements of the template may appear in the printed case report, while others are best suited for a Web Addendum.
- E. **Economic or Health Policy Articles**. These articles deal with the economics, organizational, or health policy aspects of simulation. All range in length from 1,500 to 4,000 words. Abbreviated Titles, Summary Statements, and Abstracts are required (see the section on Manuscript Preparation below).
- F. **Review Articles**. Review Articles are comprehensive papers that synthesize older ideas and suggest new ones. They may address knowledge in one or more of several areas, including but not limited to: the use of simulation for education, training, performance assessment and research; pedagogy of immersive and simulation-based learning; human factors and cognitive science related to simulation; basic science of simulation techniques and technologies. They may range in length from 2,000 to 8,000 words. Instead of a structured abstract, provide a 150 word, one or two paragraph summary of the key points of the article, along with Abbreviated Title and a short Summary Statement (see the section on Manuscript Preparation below).
- G. **Special Articles**. Articles that do not readily fall into the above categories may be published as Special Articles (e.g., history, demography, contemporary issues, etc.). Do NOT submit Abstracts, but Abbreviated Titles and Summary Statements are required (see the section on Manuscript Preparation below).
- H. **Correspondence**. Letters-to-the-Editor should be brief (250 to 1,000 words). A few references, a small table, or a pertinent illustration may be used. They require a Cover Letter and an original title on a Title Page. Do NOT submit Abbreviated Titles, Summary Statements, and Abstracts. Letters may offer criticism of published material. They must be objective and constructive. Such letters must be received in the Editorial Office no later than three months after the appearance of the original article that is the subject of the commentary. Letters also may discuss matters of general interest to the simulation healthcare community, without specific linkage to recently published articles.
- I. **Meeting Reports**. Meeting Reports are scholarly outlines of the program and content of a scientific meeting. They may be organized temporally (day by day) or thematically (topic by topic). Authors interested in submitting meeting reports should first contact the Editor to confirm that the meeting is of general interest to the readership. Meeting reports do NOT have Abstracts and should not exceed 1500 words.

- J. **Other Items.** *Simulation in Healthcare* also publishes 1) Editorials, 2) Book Reviews, 3) Web Site Reviews, and 4) Classic Papers Revisited. These are typically solicited. Please contact the Editorial Office for further information.

III. MANUSCRIPT

PREPARATION

Manuscripts must be double-spaced. Fonts should be 10 point or larger. Margins should be at least 2.5 cm (1 in) all around. If a manuscript is formatted for A4 paper, leave at least a 5 cm (2 in) margin at the bottom of the page. Number pages consecutively beginning with the Title Page.

A. General Arrangement, All Submissions

ALL submissions should be arranged in the following order.

1. Cover Letter
2. Manuscript, as a single file, consisting of Title Page, Abstract (not required for all article types - see [Types of Papers](#) section above), Body Text, References, Figure Legends (if needed)
3. Tables (each Table should be a separate file)
4. Figures (each Figure should be a separate file)
5. Supplementary Digital Content (each SDC should be a separate file)
6. Appendices (each Appendix should be a separate file)
7. Manuscripts "In Press" Information on the preparation of electronic documents and Figures can be found at the end of this Guide.

B. Cover Letter

The corresponding author must provide a Cover Letter indicating that all authors acknowledge their familiarity with these Instructions and agree to the contents of the submitted paper. The Cover Letter must also include:

1. Conflict of Interest/Financial Disclosure information in a concise statement that reflects the information contained in the Copyright Transfer and Financial Disclosure Form.
2. A statement of acknowledgments
3. A statement of funding sources
4. Identification of any specific materials recommended for Supplementary Digital Content (SDC)

C. Title Page

ALL submissions require a Title Page with the following information:

1. Article Title
2. First name, middle initial, and last name of each author, with their highest academic degree (M.D., Ph.D., etc.), academic rank (Professor, Associate Professor, etc.) and institutional affiliations.
3. Name, mailing address, phone and fax numbers, and e-mail address of the corresponding author.
4. The department and institution to which the work should be attributed.

D. Abstract (new page)

When required (see [Types of Papers](#) section), provide an Abstract of no more than 250 words. It should contain four labeled paragraphs: Introduction, Methods, Results, and Conclusions. Special Articles, Review Articles, and Concepts & Commentaries require a 150 word, one or two paragraph Summary Statement of the key points of the article (not structured). Case Reports & Simulation Scenarios need no Abstracts or Summary Statements.

E. Manuscript Body

The body of the manuscript, submitted in [one document](#) - Figures and Tables should be submitted as separate files - should typically be divided into four parts (except for Case Reports & Simulation Scenarios and Correspondence) plus references and figure legends:

1. Introduction (labeled): This should rarely exceed one page in length.
2. Methods (labeled): A subsection entitled "Statistical Analysis" should appear at the end of the Methods section when appropriate (for comments regarding Statistics see below).
3. Results (labeled).
4. Discussion (labeled).

F. References (new page)

Number references (as superscripts) in the sequence they appear in the text. Use abbreviated titles of the medical journals as they appear in Index Medicus (see <http://www.nlm.nih.gov/tsd/serials/lji.html>). Include only references accessible to all readers. Do not include articles published without peer review, or material appearing in programs of meetings or in organizational publications. Abstracts are acceptable as references only if published within the previous 3 years. Manuscripts in preparation or submitted for publication are never acceptable as references. If you cite accepted manuscripts "In Press" as references, please provide one electronic copy (e.g., Word, PDF) when you submit the new manuscript and mark them as "In Press, Reference # ____."

Use the following reference formats:

1. **Journal:** Carli F, Mayo N, Klubien K, Schricker T, Trudel J, Belliveau P: Epidural analgesia enhances functional exercise capacity and health-related quality of life after colonic surgery: Results of a randomized trial. *Anesthesiology* 2002; 97:540-9

2. **Book:** Barash PG, Cullen BF, Stoelting RK: Clinical Anesthesia, 3rd edition. Philadelphia, Lippincott-Raven Publishers, 1997, pp 23-4.
3. **Chapter:** Blitt C: Monitoring the anesthetized patient, Clinical Anesthesia, 3rd edition. Edited by Barash PG, Cullen BF, Stoelting RK. Philadelphia, Lippincott-Raven Publishers, 1997, pp 563-85.
4. **Website:** Author (if one exists). International Society for Infectious Diseases. ProMED-mail Web site. <http://www.promedmail.org>. Accessed April 29, 2004.

H. **Tables**

Number tables consecutively in order of appearance (Table 1, etc.). Each Table should be submitted as a separate Table file. Each table must have a title and a caption. Tables should be submitted as Word documents. Do not submit tables as image files or spreadsheets.

I. **Figures**

Figures should be prepared according to the professional standards of this Journal. Each Figure should be submitted as a separate Figure file, clearly labeled with the figure number (e.g., Figure1.tif, Figure2.eps, etc.). Number the figures consecutively in order of appearance (Figure 1, etc.). If a single figure contains more than one panel, each panel must be identified alphabetically (e.g., Figure 1A, Figure 1B, etc.) and should read left to right in presentation. The figures must be cited in the text in the same, consecutive numeric order. **Note:** Due to production requirements, differently formatted figures may be required for accepted articles. Color figures are welcome during the review phase. **However, while color figures can be published, the increased cost of printing must be borne by the authors. If you do not wish for your color figures to be published in color, please let the Editorial Office know and we'll convert them to black and white.**

Detailed directions regarding acceptable file formats can be found below in the SUBMISSION OF ELECTRONIC DOCUMENTS section

J. **Figure**

Legends

Supply a legend for each figure; all legends should be grouped on a single page or series of pages separate from the figures under the heading Figure Legends. Figure legends should be submitted within the Manuscript file following the references.

K. **Supplemental**

Digital

Content

(SDC)

Authors may submit supplemental digital content (SDC) to enhance their article's text and to be considered for online-only posting. SDC may include the following types of content: text documents, graphs, tables, figures, audio, and video.

SDC must be called out consecutively in the text. SDC call-outs should include the type of material submitted (Audio, Figure, Table, Video, etc.), should be clearly labeled as "Supplemental Digital Content," should include a sequential number, and should provide a brief description of the supplemental content. For example:

We performed many tests on the degrees of flexibility in the elbow (see Video, Supplemental Digital Content 1, which demonstrates elbow flexibility) and found our results inconclusive.

Each SDC file must be composed to stand alone. For example, tables and figures must include titles, legends, and/or footnotes, following journal style, so the viewer can fully understand the supplemental content on its own. Production will not make any edits to the supplemental files; they will be presented as submitted.

A listing of SDC must be submitted at the end of the manuscript file following the Figure Legends (or references if there are no figures). Include the SDC number, file type of the SDC, and a description of the SDC. This text will be removed by our production staff and not published. For example:

Supplemental Digital Content 1. wmv, video of elbow flexibility

Authors should mask patients' eyes and remove patients' names from SDC unless they obtain written consent from the patients and submit written consent with the manuscript. Copyright for video or audio SDC will be required upon acceptance. **All acceptable file types are permissible up to 10 MB's. For audio or video files greater than 10 MB's, authors should first query the Journal office for approval. For a list of acceptable file types and size limits, please review LWW's requirements for submitting SDC: <http://links.lww.com/A142>**

L. **Appendices**

Number each appendix and place after the Tables and Figures. Appendices should continue the same page number sequence as the body of the article. Each appendix must be cited within the text, in consecutive order. If there are more than one appendices, start each on a new page.

M. **Manuscripts**

"In

Press"

Please submit an electronic copy (Word, PDF) of any "In Press" manuscript that is cited in the reference list, labeled as "In Press, Reference # ____."

N. **Spelling**

and

Terminology

Per the Journal's policy [see editorial "What's in a Name"] the preferred spelling for a simulation device known as a 'mannequin' is 'mannequin' (and NOT 'manikin'). However, if authors prefer to use 'manikin' they may request this.

Authors should NOT use the term "human patient simulation", "human patient simulator", or the abbreviation "HPS" except in 2 circumstances:

I) They are referring to the specific trademarked simulation device marketed by METI as the "human patient simulator (HPS)" or II) They are making a distinction between simulation in veterinary medicine vs. simulation in human medicine. Except for these circumstances it is assumed that all patient simulation is about human patients, and the terms "patient simulation" or "patient simulator" should be used rather than "human patient simulation" or "human patient simulator". This usage will prevent confusion as to unwarranted reference to a specific commercial product.

O. **Additional Information**

1. **Units of Measurement:** Use metric units. The units for pressures are mmHg or cmH₂O. Diagonal slashes are acceptable for simple units, e.g., mg/kg; when more than two items are present, negative exponents should be used, i.e., ml * kg⁻¹ * min⁻¹ instead of ml/kg/min.
2. **Abbreviations:** Define all abbreviations except those approved by the International System of Units for length, mass, time, temperature, amount of substance, etc. Do not create new abbreviations for drugs, procedures, experimental groups, etc.
3. **Drug Names and Equipment:** Use generic names. If a brand name must be used, insert it in parentheses after the generic name. Provide manufacturer's name, city, state, and country. Be careful about the use of trademarked terms (e.g., Thrombelastography™, TEG™, etc.).
4. **Statistics:** Detailed statistical methodology must be reported. Describe randomization procedures and the specific tests used to examine each part of the results; do not simply list a series of tests. Care should be taken with respect to a) parametric vs. nonparametric data, b) corrections for multiple comparisons, and c) rounding errors (summary statistics should not contain more significant digits than the original data). Median range (or percentiles) is preferred for nonparametric data.
5. **Patient Identification:** Do not use patients' names, initials, or hospital numbers. An individual (other than an author) must not be recognizable in photographs unless written consent of the subject has been obtained and is provided at the time of submission.
6. **Permissions:** Written permission must be obtained from the original publisher (or author if the author owns the copyright) if any figure or table from a previously-published document is used. Contact the Editorial Office for further information.

IV. SUBMISSION OF ELECTRONIC DOCUMENTS

All manuscripts must be submitted on-line using the Journal's Editorial Manager (EM) System website at <https://sih.edmgr.com>. Please read the following material carefully.

First-time users: Please click the Register button from the menu above and enter the requested information. On successful registration, you will be sent an e-mail indicating your user name and password. Print a copy of this information for future reference. Note: If you have received an e-mail from us with an assigned user ID and password, or if you are a repeat user, do not register again. Just log in. Once you have an assigned ID and password, you do not have to re-register, even if your status changes (that is, author, reviewer, or editor).

Authors: Please click the log-in button from the menu at the top of the page and log in to the system as an Author. Submit your manuscript according to the author instructions. You will be able to track the progress of your manuscript through the system. If you experience any problems, please contact Karl W. Durst, Managing Editor, at journal@ssih.org.

- A. **File** **Formats,** **Text**
Textual material (Body text, Figure Legends, etc.) can be submitted in any of the following formats:

- Microsoft Word for Windows or Macintosh, any version (.doc)
- WordPerfect for Windows, any version (.wpf)
- Other word processing programs can be used, but save documents in ASCII text (.txt), RichTextFormat (.rtf), or Word (.doc)

Use standard file extensions, e.g., .doc, .rtf, .txt.

- B. **File** **Formats,** **Fonts**
When files are received, they will be converted into PDF format. Problems can arise if the parent document contains fonts that cannot be converted. This is a particular problem with Asian fonts. To avoid difficulties, we ask that authors prepare their documents using one or more of the fonts listed below. These fonts should be used in the Body Text of the paper, as well as for all Tables and Figures. Acceptable fonts include: Arial, Palatino, Bookman, Times Courier, Times New Roman, Georgia, Verdana, Helvetica

Special characters should be created with: Symbol, Wingdings, Webdings
Zapf Dingbats

- C. **File** **Formats,** **Graphics/Images**
Graphics/Images (half-tones, color pictures, scientific graphics) **MUST** be submitted in one of the following formats:

- TIFF (.tif)
- Encapsulated Postscript (.eps)
- PowerPoint (.ppt)

Please note that artwork generated from office suite programs such as Corel Draw and MS Word and artwork downloaded from the Internet (JPEG or GIF files) CANNOT be used.

Line art must have a resolution of at least 1200 DPI (Dots Per Inch), and electronic photographs—radiographs, CT scans, etc.—and scanned images must have a resolution of at least 300 DPI. If fonts are used in the artwork, they must be converted to paths or outlines or they must be embedded in the files. *Color images must be created/scanned and saved and submitted as CMYK files, not RGB.* For help with saving color figures as CMYK files please follow the instructions at <http://edmgr.ovid.com/www-final/accounts/5StepsforArt.pdf>.

**If you can't save your color figures in CMYK and you don't want to publish them color, you can convert your RGB files to grayscale by following these instructions:*

Using	Adobe	Photoshop	(raster):
Image->Mode->Grayscale			
Using	Adobe	Illustrator	(vector):

1. File->Document Color Mode->CMYK Color
 2. Select All, Edit->Edit Colors->Convert to Grayscale
**If you are having problems getting your TIFF or EPS figure files to pass the EM quality control test, try saving them as PPT files. This usually helps.*
 - D. File Sizes

Manuscripts will be distributed to reviewers *via* the Web. However, reviewers who use telephone modems may experience unacceptable download delays if the files are too large. A number of simple tricks can be used to avoid unnecessarily large files. Do not scan pages of text. Do not scan printed Figures unless no original digital document exists. If a scanned figure is unavoidable, please use Adobe PhotoShop or a similar program to edit the file and reduce the file size (not necessarily the image size) as much as possible before submission. For example, crop the picture to exclude surrounding "white space." Do not carelessly use color. Black and white line drawings or gray-scale figures should not be saved as color documents; this will increase file sizes without increasing the information content of the file. Do not use color unless absolutely needed to convey information. Do not use compression software (Zip, Stuffit) to reduce a final file size.
- V. PRE-PUBLICATION MEDIA ATTENTION
- Journal articles are embargoed until published. Do not issue press releases or hold press conferences about articles to be published. Instruct journalists and media representatives that articles are embargoed until the publication mailing date. Articles that are described extensively by the media prior to publication may be pulled from the Journal of Record and the author(s) may be sanctioned by the Journal (e.g. not be allowed to submit manuscripts for one year or more).

9.6ANEXO F- INSTRUMENTO “*Medication Counseling Behavior Guidelines*” (USP, 1997-1999)

ADAPTADO TRANSCULTURALMENTE PARA O PORTUGUÊS (Santos, 2013)

GUIA COMPORTAMENTAL DE ORIENTAÇÃO SOBRE MEDICAMENTOS

CATEGORIA 1: ÍTENS REFERENTES À INTRODUÇÃO DA ORIENTAÇÃO

	N/A	Não feita	Péssimo	Insatisfatório			Satisfatório		Excelente		
1. No início, conduz a orientação, apresentando-se e identificando quem é o paciente ou o seu responsável	-	1	2	3	4	5	6	7	8	9	10
2. Explica a finalidade da orientação	-	1	2	3	4	5	6	7	8	9	10
3. Revisa a prescrição do paciente antes da orientação	-	1	2	3	4	5	6	7	8	9	10
4. Obtém informações prévias e pertinentes relacionadas ao medicamento (por exemplo, idade, alergias, outros medicamentos, gravidez, amamentação)	-	1	2	3	4	5	6	7	8	9	10
5. Adverte o paciente sobre o uso de outros medicamentos ou substâncias, incluindo medicamentos isentos de prescrição (MIPs), fitoterápicos e bebidas alcoólicas, os quais poderiam interagir com o medicamento prescrito (aumentando, diminuído ou anulando sua ação)	-	1	2	3	4	5	6	7	8	9	10
6. Avalia se o paciente tem outras condições clínicas as quais poderiam influenciar os efeitos desse medicamento ou a probabilidade de uma reação adversa	-	1	2	3	4	5	6	7	8	9	10
7. Avalia a compreensão do paciente (ou do responsável) sobre o(s) motivo(s) da farmacoterapia prescrita	-	1	2	3	4	5	6	7	8	9	10
8. Avalia quaisquer preocupações reais e/ou problemas potenciais do paciente	-	1	2	3	4	5	6	7	8	9	10

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CATEGORIA 2: ÍTENS REFERENTES AO CONTEÚDO DA ORIENTAÇÃO

	N/A	Não feita	Péssimo	Insatisfatório			Satisfatório		Excelente		
9. Discute o nome e a indicação do medicamento	-	1	2	3	4	5	6	7	8	9	10
10. Explica a posologia, incluindo o horário de utilização e a duração da terapia, quando apropriado	-	1	2	3	4	5	6	7	8	9	10
11. Auxilia o paciente (ou o responsável) no desenvolvimento de um plano de cuidados para incorporar a farmacoterapia à sua rotina	-	1	2	3	4	5	6	7	8	9	10
12. Explica quanto tempo levará para o medicamento fazer efeito	-	1	2	3	4	5	6	7	8	9	10
13. Discute as recomendações de armazenamento e instruções complementares (por exemplo, agitar bem, manter refrigerado)	-	1	2	3	4	5	6	7	8	9	10
14. Enfatiza os benefícios da utilização do medicamento conforme prescrito	-	1	2	3	4	5	6	7	8	9	10
15. Alerta sobre os efeitos adversos potenciais (significativos) dos medicamentos	-	1	2	3	4	5	6	7	8	9	10
16. Discute como prevenir ou controlar os efeitos adversos do medicamento, caso ocorram	-	1	2	3	4	5	6	7	8	9	10
17. Discute as precauções associadas ao uso do medicamento (por exemplo, evitar operar máquinas ou dirigir)	-	1	2	3	4	5	6	7	8	9	10
18. Discute as interações significativas entre medicamento-medicamento, medicamento-alimento e medicamento-doença	-	1	2	3	4	5	6	7	8	9	10

19. Explica detalhadamente o que fazer se o paciente esquecer de utilizar uma dose	-	1	2	3	4	5	6	7	8	9	10
20. Discute com o paciente (ou o responsável) os potenciais problemas em tomar o medicamento conforme prescrito (por exemplo, custo, acesso)	-	1	2	3	4	5	6	7	8	9	10
21. Ajuda o paciente (ou o responsável) a gerar soluções para os problemas potenciais	-	1	2	3	4	5	6	7	8	9	10
22. Fornece informações detalhadas sobre a farmacoterapia	-	1	2	3	4	5	6	7	8	9	10

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CATEGORIA 3: ÍTENS REFERENTES AO PROCESSO DA ORIENTAÇÃO

	N/A	Não feita	Péssimo	Insatisfatório			Satisfatório		Excelente		
23. Usa linguagem acessível ao paciente (ou ao responsável)	-	1	2	3	4	5	6	7	8	9	10
24. Usa conhecimentos embasados na literatura para dar suporte durante a orientação ao paciente (ou ao responsável)	-	1	2	3	4	5	6	7	8	9	10
25. Responde com compreensão e empatia	-	1	2	3	4	5	6	7	8	9	10
26. Apresenta fatos e conceitos em uma ordem lógica	-	1	2	3	4	5	6	7	8	9	10
27. Mantém o controle e o direcionamento da orientação	-	1	2	3	4	5	6	7	8	9	10
28. Investiga informações adicionais (por exemplo, hábitos de vida, crenças)	-	1	2	3	4	5	6	7	8	9	10
29. Utiliza perguntas abertas	-	1	2	3	4	5	6	7	8	9	10
30. De maneira geral, apresenta comportamentos não-verbais efetivos:	-	1	2	3	4	5	6	7	8	9	10

30 a. Contato visual apropriado	-	1	2	3	4	5	6	7	8	9	10
30 b. Voz é audível; tom e velocidade da fala são bons	-	1	2	3	4	5	6	7	8	9	10
30 c. Linguagem corporal, posturas e gestos confirmam a mensagem falada	-	1	2	3	4	5	6	7	8	9	10
30 d. Distância entre o profissional de saúde e o paciente (ou o responsável) é apropriada	-	1	2	3	4	5	6	7	8	9	10

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CATEGORIA 4: ÍTENS REFERENTES À CONCLUSÃO DA ORIENTAÇÃO

	N/A	Não feita	Péssimo	Insatisfatório			Satisfatório		Excelente		
31. Verifica a compreensão do paciente, através de feedback (retorno da informação)	-	1	2	3	4	5	6	7	8	9	10
32. Resume, reconhecendo e/ou enfatizando os pontos-chave da informação	-	1	2	3	4	5	6	7	8	9	10
33. Fornece uma oportunidade para preocupações ou perguntas finais	-	1	2	3	4	5	6	7	8	9	10
34. Ajuda o paciente a planejar o acompanhamento e os próximos passos	-	1	2	3	4	5	6	7	8	9	10

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9.7ANEXO G. Lista de grupos e indicações terapêuticas especificadas (GITE).

Grupos Terapêuticos	Indicações Terapêuticas	Observações
Antiacnéicos tópicos e adstringentes	acne, acne vulgar, rosácea, espinhas	Restrição: retinóides
Antiácidos, Antieméticos, Eupépticos, Enzimas digestivas	acidez estomacal, azia, desconforto estomacal, dor de estômago, dispepsia, enjôo, náusea, vômito, epigastria, má digestão, queimação	Restrições: metoclopramida, bromoprida, mebeverina, inibidor da bomba de próton
Antibacterianos tópicos	infecções bacterianas da pele	Permitidos: bacitracina e neomicina
Antidiarréicos	diarréia, disenteria	Restrições: loperamida infantil, opiáceos
Antiespasmódicos	cólica, cólica menstrual, dismenoréia, desconforto pré-menstrual, cólica biliar/renal/intestinal	Restrição: Mebeverina
Anti-histamínicos	alergia, coceira / prurido, coriza, rinite alérgica, urticária, picada de inseto, ardência, ardor, conjuntivite alérgica, prurido senil, prurido ocular alérgico, febre do feno, dermatite atópica, eczemas	Restrições: adrenérgicos, corticóides que não a hidrocortisona de uso tópico
Anti-seborréicos	caspa, dermatite seborréica, seborréia, oleosidade	—
Anti-sépticos orais, anti-sépticos buco-faríngeos	aftas, dor de garganta, profilaxia das cáries	—
Anti-sépticos nasais, fluidificantes nasais, umectantes nasais	anti-sépticos nasais, fluidificantes nasais, umectantes nasais	—
Anti-sépticos oculares	—	Restrições: adrenérgicos, (exceto nafazolina com concentração < 0,1%), corticóides

Anti-sépticos da pele e mucosas	assaduras, dermatite de fraldas, dermatite de contato, dermatite amoniacal, intertrigo	—
Anti-sépticos urinários	disúria, dor / ardor / desconforto para urinar	—
Anti-sépticos vaginais tópicos	higiene íntima, desodorizante	—
Antiinflamatórios	lombalgia, mialgia, torcicolo, dor articular, artralgia, inflamação da garganta, dor muscular, dor na perna, dor varicosa, contusão, hematomas, entorses	Permitidos: naproxeno, ibuprofeno, cetoprofeno
Antiflebites	dor nas pernas, dor varicosa, sintomas de varizes, dores nas pernas relacionadas à varizes, dores após escleroterapia venosa	—
Antifisético, antiflatulentos, carminativos	eructação, flatulência, empachamento, estufamento, aerofagia pós-operatória, gases, meteorismo	—
Antifúngico, antimicóticos	micoses de pele, frieira, micoses de unha, pano branco, infecções fúngicas das unhas, onicomicoses, dermatomicoses	Permitidos: tópicos
	ptíriase versicolor, tinea das mãos, tinea dos pés, pé de atleta, tinea do corpo, micose de praia, tinea da virilha	
	candidíase cutânea, monilíase cutânea, dermatite seborréica, dermatomicoses superficiais, vulvovaginites, dermatite	
Anti-hemorroidários	sintomas de hemorróidas	Permitidos: tópicos
Antiparasitários orais, anti-helmínticos	verminoses	Permitidos: mebendazol, levamisol.
Antiparasitários tópicos, escabícidas, ectoparasitícidas	piolhos, sarna, escabiose, carrapatos, pediculose, lêndeas	—
Antitabágicos	alívio dos sintomas decorrente do abandono do hábito de fumar, alívio dos sintomas da síndrome de abstinência	Restrição: bupropiona

Analgésicos, Antitérmicos, Antipiréticos	dor, dor de dente, dor de cabeça, dor abdominal e pélvica, enxaqueca, sintomas da gripe, sintomas dos resfriados, febre, cefaléia, dores reumáticas, nevralgias	Permitidos: analgésicos (exceto narcóticos)
	Lombalgia, mialgia, torcicolo, dor articular, artralgia, inflamação da garganta, dor muscular, contusão	
	hematomas, entorses, tendinites, cotovelo de tenista, lumbago, dor pós-traumática, dor ciática, bursite, distensões	
Ceratolíticos	descamação, esfoliação da pele, calos, verrugas, verruga plantar, verruga vulgar	—
Cicatrizantes	feridas, escaras, fissuras de pele e mucosas, rachaduras	—
Colagogos, Coleréticos	distúrbios digestivos, distúrbios hepáticos	—
Descongestionantes nasais tópicos	congestão nasal, obstrução nasal, nariz entupido	Restrições: vasoconstritores
Descongestionantes nasais sistêmicos	congestão nasal, obstrução nasal, nariz entupido	Permitido: Fenilefrina