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Validation of quality indicators for evaluating geriatric pharmacotherapy services in primary care: a mixed methods study

Noriko Sato [1], Kenji Fujita [2], Hiroshi Okada [3], Kazuki Kushida [4], Timothy F Chen [1]

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[1]Faculty of Medicine and Health, The University of Sydney School of Pharmacy, Sydney, New South Wales, Australia
[2]Kolling Institute, Faculty of Medicine and Health, The University of Sydney and the Northern Sydney Local Health District, Sydney, New South Wales, Australia
[3]Department of Health Informatics, Kyoto University School of Public Health, Kyoto, Japan
[4]Faculty of Pharmacy, Showa Pharmaceutical University, Machida, Tokyo, Japan

Correspondence to
Dr Noriko Sato;
noriko.sato@sydney.edu.au

ABSTRACT

Objective To assess measurement properties of 121 face and content validated quality indicators (QIs) for medication safety in geriatric pharmacotherapy in primary care.

Design A mixed methods study: a 6-month observational study in primary care (July–December 2020) and in-depth semistructured online interviews with participants (February–March 2021).

Setting Sixty community pharmacies in Japan.

Participants Patients aged 75 years and older who were regularly taking six or more prescription medicines for >4 weeks were eligible. The observational study included 457 patients. The interviews were undertaken with 26 community pharmacists, including pharmacy managers and owners.

Primary and secondary outcome measures Five measurement properties of QIs (applicability, improvement potential, acceptability, implementation issues and sensitivity to change) were evaluated. A web application was developed for data reporting and data visualisation.

Results This study showed that 53 QIs met the measurement properties of applicability, improvement potential, acceptability and implementation issues. Of 53 QIs, 17 also had a high sensitivity to change. Interviews identified eight themes (indicator characteristics, web application, policy, patient, time, competence, pharmacy administration and collaboration) in relation to the consequence of implementation of QIs.

Conclusions A set of 121 QIs for geriatric pharmacotherapy was field tested for their five measurement properties. This QI set can be used to identify patients who may benefit from clinician reviews of their medicines. These QIs may be applied at different levels within the healthcare system: patient, pharmacy, regional and national levels. Further mechanisms to automatically collect and report data should be established to facilitate sustainable quality improvement initiatives.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This study was the first to validate a comprehensive set of quality indicators (QIs) for medication safety in geriatric pharmacotherapy across 17 different disease states in primary care in patients with polypharmacy.
⇒ The multistep, mixed methods process for the evaluation of the measurement properties (applicability, improvement potential, sensitivity to change, acceptability and implementation issues) was applied.
⇒ Even though a web application was developed for QI score calculation and visualisation, data were self-reported by pharmacists, which might have led to a reporting bias.

INTRODUCTION

Polypharmacy and inappropriate use of medicines are associated with an increased risk of adverse drug reactions and drug interactions.[1–4] As most medicines are prescribed and used in primary care, the quality of primary care services is increasingly important to minimise harm from medicine use.

Community pharmacists are one of the most accessible primary healthcare professionals as appointments are generally not required, the long opening hours of pharmacies and their community-based locations.[5 6] Community pharmacists are also generally the last healthcare professional who patients see before they start or continue taking their medicines. Community pharmacists therefore have a significant professional role in contributing to medication safety in older people by reducing the use of potentially inappropriate medicines and resolving drug-related problems (DRPs).[7 8]

In 2005, the Japan Geriatrics Society published its first guideline for geriatric pharmacotherapy.[9] This guideline was updated in 2015,[10] in line with the Beers Criteria[11] and Screening Tool of Older Person's Potentially Inappropriate Prescriptions.[12 13] This guideline aimed to maximise the benefits of medicine use in older people and minimise the risk of harm. In 2018 and 2019, two policy guidance documents were developed by the Japanese Ministry of Health, Labour and

Welfare, in collaboration with the Japan Geriatrics Society, to reduce the problems associated with polypharmacy.[14 15] These guidance documents were designed for healthcare professionals, including pharmacists, to ensure optimal use of medicines for people aged over 75 years.

Despite national recommendations designed to support healthcare professionals, polypharmacy and inappropriate use of medicines remain a significant problem in Japan.[16] Furthermore, a validated mechanism for measuring the quality of care (ie, adherence to recommendations) is lacking. Therefore, an initial validation (face and content) of a set of quality indicators (QIs) for geriatric pharmacotherapy services provided by community pharmacists was recently developed and conducted, involving a literature review, national guideline review and two sets of modified Delphi studies.[17] The aim of this study was to assess the five measurement properties of this set of QIs.

METHODS

A field test was undertaken to evaluate the measurement properties (applicability, improvement potential, acceptability, implementation issues and sensitivity to change) of a set of 121 face and content validated QIs designed to assess geriatric pharmacotherapy service provision by community pharmacists using a mixed-method approach. This involved an observational study in primary care (July–December 2020) and qualitative interviews with participants (February–March 2021) (see figure 1 for study flow diagram). This study was reported in accordance with the Strengthening the Reporting of Observational Studies in Epidemiology statement[18] and the Consolidated criteria for Reporting Qualitative research checklist.[19]

Characteristics of QIs

QIs are usually described with denominator and numerator and measured as a percentage. A higher QI score denotes a high quality of care (ie, good process or outcome of care). In this study, the 121 QIs were either medicine-specific indicators (n=110) or general indicators (n=11) (table 1). For instance, a QI about 'laboratory monitoring of warfarin' was classified as medicine-specific indicator, whereas a QI about 'assessment of transitional care' was categorised as general indicator. The medicine-specific indicators were classified into the Anatomical Therapeutic Chemical (ATC) classification system,[20] covering 131 third-level ATC codes (see online supplemental appendix 1). All QIs were also classified according to Donabedian's framework: structure (n=0), process (n=109) or outcome (n=12).[21] The QIs were also mapped to the classification system for DRPs developed by the Pharmaceutical Care Network Europe.[22]

Observational study

Setting

Community pharmacies were purposively recruited via direct and indirect means (ie, face to face, phone call, website and social media) with the guidance of experts in the field of community pharmacy. A sample size of 50 pharmacies was estimated to allow for sufficient diversity in terms of location (eg, urban and rural) and ownership (eg, chain and independent).[23] A kick-off meeting was held on 11 February 2020 to train community pharmacists

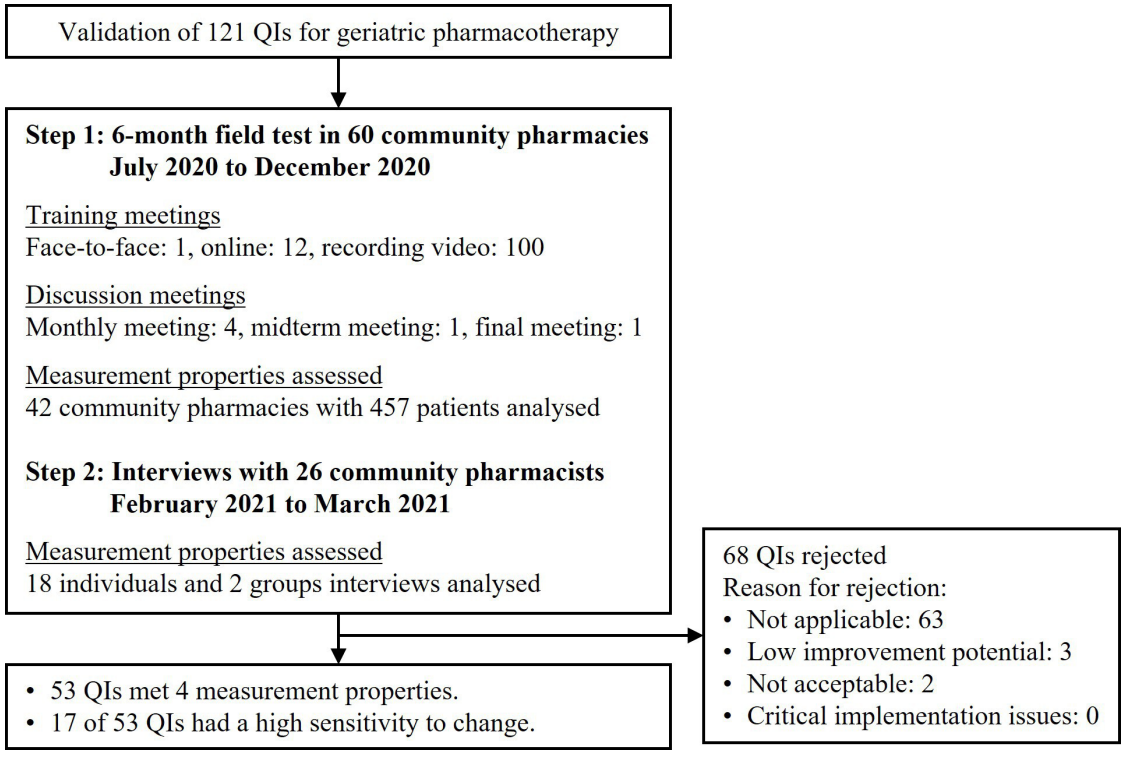


Figure 1 Study flow diagram. QIs, quality indicators.

Table 1 Measurement properties of 121 QIs for geriatric pharmacotherapy

No. Quality indicators by therapeutic area	Type	QI score (%) (numerator/ denominator)	Applicability (%)	Improvement potential (%)	Sensitivity to change (%)
Sedative hypnotics/anxiolytics					
1. ADR monitoring: benzodiazepines	Process	73 (94/128)	28	27	21*
2. Guidance: benzodiazepines	Process	53 (66/124)	27	47	31***
3. Drug–drug interactions: sedative hypnotics, anxiolytics	Process	56 (9/16)	4	44	N/A
Antidepressants					
4. Drug–disease interactions: antidepressants	Process	58 (11/19)	4	42	N/A
5. Drug–drug interactions: antidepressants	Process	46 (6/13)	3	54	N/A
6. ADR monitoring: TCAs	Process	50 (1/2)	0.4	50	N/A
7. Drug–disease contraindications: TCAs, maprotiline	Process	0 (0/2)	0.4	100	N/A
8. Drug–disease contraindications: TCAs, escitalopram	Process	0 (0/3)	0.7	100	N/A
9. ADR monitoring: sulpiride	Process	33 (2/6)	1	67	N/A
10. Medication appropriateness review: sulpiride	Process	0 (0/6)	1	100	N/A
11. ADR monitoring: SSRIs	Process	47 (7/15)	3	53	N/A
12. Guidance: SSRIs	Process	53 (8/15)	3	47	N/A
Drugs for BPSD					
13. ADR monitoring: antipsychotics	Process	65 (11/17)	4	35	N/A
14. ADR monitoring: yokukansan	Process	43 (3/7)	2	57	N/A
15. Drug–disease contraindications: butyrophenones	Process	– (0/0)	–	–	–
16. Drug–disease contraindications: atypical antipsychotics	Process	100 (4/4)	0.9	0	N/A
Antihypertensives					
17. Medication appropriateness review: α-blockers	Process	28 (8/29)	6	72	0
18. Drug–drug interactions: CCBs	Process	65 (22/34)	7	35	0
19. Medication adherence: ACE inhibitors, ARBs 1	Process	63 (40/64)	14	38	10
20. Medication adherence: ACE inhibitors, ARBs 2	Outcome	91 (232/255)	56	9	N/A
21. Medication appropriateness review: antihypertensives	Process	36 (53/147)	32	64	10
22. Medication appropriateness: antihypertensives	Outcome	94 (364/389)	85	6	N/A
Antidiabetics					
23. Medication appropriateness review: sulfonylureas	Process	17 (10/58)	13	83	0.1
24. Medication appropriateness: sulfonylureas	Outcome	59 (92/155)	34	41	-6
25. ADR monitoring: sulfonylureas, self-injecting insulin	Process	83 (60/72)	16	17	-2
26. Drug–drug interactions: sulfonylureas, glinides	Process	54 (7/13)	3	46	N/A
27. ADR monitoring: biguanides	Process	82 (63/77)	17	18	-2
28. Medication appropriateness review: thiazolidinediones	Process	17 (2/12)	3	83	N/A
29. ADR monitoring: α-glucosidase inhibitors	Process	71 (20/28)	6	29	19
30. ADR monitoring: SGLT2 inhibitors	Process	73 (30/41)	9	27	8
31. Guidance: SGLT2 inhibitors	Process	51 (22/43)	9	49	31*
32. Medication appropriateness review: SGLT2 inhibitors	Process	42 (10/24)	5	58	14
33. Laboratory monitoring: antidiabetics	Process	75 (121/161)	35	25	5
Antihyperlipidemics					
34. ADR monitoring: statins	Process	66 (176/266)	58	34	10*
35. Drug–drug interactions: statins	Process	41 (7/17)	4	59	N/A
36. Drug–drug contraindications: statins	Process	54 (88/164)	36	46	23***
37. Drug–drug interactions: statins, fibrates	Process	52 (13/25)	6	48	0
38. Medication appropriateness: antihyperlipidemics	Outcome	93 (264/285)	62	7	N/A

Continued

Table 1 Continued

No. Quality indicators by therapeutic area	Type	QI score (%) (numerator/ denominator)	Applicability (%)	Improvement potential (%)	Sensitivity to change (%)
Anticoagulants					
39. Drug–disease contraindications: DOACs	Process	37 (23/63)	14	64	7
40. Drug–drug interactions: DOACs	Process	88 (30/34)	7	12	0
41. Drug–drug contraindications: dabigatran	Process	56 (5/9)	2	44	N/A
42. Laboratory monitoring: warfarin	Process	45 (13/29)	6	55	0
43. Guidance: warfarin	Process	76 (22/29)	6	24	12
Antiulcers					
44. ADR monitoring: H2 blockers	Process	25 (13/53)	12	76	2
45. Drug–drug interactions: PPIs	Process	50 (11/22)	5	50	N/A
46. Medication appropriateness: PPIs	Outcome	83 (209/253)	55	17	2
Anti-inflammatories					
47. ADR monitoring: acetaminophen	Process	50 (9/18)	4	50	N/A
48. Drug–drug interactions: NSAIDs 1	Process	50 (20/40)	9	50	-8
49. Drug–drug interactions: NSAIDs 2	Process	29 (19/66)	14	71	18
50. Medication appropriateness review: NSAIDs 1	Process	17 (7/41)	9	83	5
51. Medication appropriateness review: NSAIDs 2	Process	19 (7/37)	8	81	N/A†
52. Medication appropriateness: NSAIDs	Outcome	56 (37/66)	14	44	N/A†
Antimycobacterials/antivirals					
53. ADR monitoring: antibiotics/antivirals excreted by the kidney	Process	– (0/0)	–	–	–
54. Drug–drug contraindications: carbapenems	Process	– (0/0)	–	–	–
55. Drug–drug interactions: fluoroquinolones	Process	0 (0/1)	0.2	100	N/A
56. Guidance: tetracyclines, fluoroquinolones	Process	100 (1/1)	0.2	0	N/A
Laxatives					
57. ADR monitoring: magnesium oxide	Process	56 (58/104)	23	44	23*
Anticholinergics					
58. ADR monitoring: anticholinergics	Process	54 (46/86)	19	47	17
Antidementia drugs					
59. ADR monitoring: memantine 1	Process	80 (4/5)	1	20	N/A
60. ADR monitoring: memantine 2	Process	83 (5/6)	1	17	N/A
61. Medication appropriateness review: memantine	Process	0 (0/1)	0.2	100	N/A
62. Medication appropriateness: memantine	Outcome	100 (1/1)	0.2	0	N/A
63. Guidance: rivastigmine	Process	– (0/0)	–	–	–
64. ADR monitoring: rivastigmine	Process	– (0/0)	–	–	–
65. ADR monitoring: ChEIs	Process	27 (9/34)	7	74	11
66. Drug–drug interactions: ChEIs 1	Process	44 (4/9)	2	56	N/A
67. Drug–disease interactions: ChEIs	Process	36 (4/11)	2	64	N/A
68. Drug–drug interactions: ChEIs 2	Process	50 (2/4)	0.9	50	N/A
69. Drug–drug interactions: ChEIs 3	Process	0 (0/2)	0.4	100	N/A
70. Medication appropriateness review: ChEIs	Process	0 (0/8)	2	100	N/A
71. Medication appropriateness: ChEIs	Outcome	71 (25/35)	8	29	0
72. Medication administration for those with dementia 1	Process	53 (20/38)	8	47	12
73. Medication administration for those with dementia 2	Process	18 (3/17)	4	82	N/A
Osteoporosis drugs					
74. Drug–disease contraindications: bisphosphonates	Process	69 (27/39)	9	31	36*

Continued

Table 1 Continued

No. Quality indicators by therapeutic area	Type	QI score (%) (numerator/ denominator)	Applicability (%)	Improvement potential (%)	Sensitivity to change (%)
75. Duplications: bisphosphonates	Process	38 (15/40)	9	63	17
76. Guidance: bisphosphonates, denosumab	Process	35 (14/40)	9	65	37**
77. Laboratory monitoring: denosumab	Process	25 (1/4)	0.9	75	N/A
78. Medication appropriateness review: raloxifene, bazedoxifene	Process	40 (4/10)	2	60	N/A
79. Treatment duration: teriparatide	Process	0 (0/1)	0.2	100	N/A
80. Medication appropriateness review: teriparatide	Process	0 (0/1)	0.2	100	N/A
81. Medication appropriateness: teriparatide	Outcome	0 (0/1)	0.2	100	N/A
82. Drug–drug interactions: vitamin D	Process	16 (3/19)	4	84	N/A
83. Medication appropriateness review: alfacalcidol	Process	18 (2/11)	2	82	N/A
84. Medication appropriateness: alfacalcidol	Outcome	74 (20/27)	6	26	0**
COPD drugs					
85. Medication appropriateness review: oral corticosteroids	Process	14 (1/7)	2	86	N/A
86. Drug–disease contraindications: LAMAs	Process	89 (16/18)	4	11	N/A
87. Drug–disease interactions: LAMAs	Process	60 (6/10)	2	40	N/A
88. ADR monitoring: LABAs	Process	42 (11/26)	6	58	20
89. Drug–disease interactions: LABAs	Process	28 (9/32)	7	72	6
90. Drug–drug interactions: LABAs	Process	25 (1/4)	0.9	75	N/A
91. ADR monitoring: theophylline	Process	40 (6/15)	3	60	N/A
92. Laboratory monitoring: theophylline	Process	7 (1/15)	3	93	N/A
93. Drug–drug interactions: theophylline	Process	0 (0/2)	0.4	100	N/A
94. Guidance: steroid inhalers	Process	72 (23/32)	7	28	5
95. Guidance: inhalers	Process	62 (24/39)	9	39	8
Analgesics for cancer pain					
96. ADR monitoring: NSAIDs	Process	0 (0/3)	0.7	100	N/A
97. ADR monitoring: opioids	Process	100 (1/1)	0.2	0	N/A
98. Laboratory monitoring: opioids	Process	– (0/0)	–	–	–
99. Drug–drug interactions: opioids 1	Process	100 (1/1)	0.2	0	N/A
100. Drug–drug interactions: opioids 2	Process	0 (0/1)	0.2	100	N/A
101. Drug–drug interactions: opioids 3	Process	– (0/0)	–	–	–
102. ADR monitoring: antipsychotics	Process	100 (1/1)	0.2	0	N/A
103. ADR monitoring: pregabalin	Process	40 (2/5)	1	60	N/A
104. Pain management	Process	50 (2/4)	0.9	50	N/A
Other drugs					
105. ADR monitoring: digitalis	Process	0 (0/1)	0.2	100	N/A
106. Laboratory monitoring: digitalis	Process	0 (0/1)	0.2	100	N/A
107. Medication appropriateness: digitalis	Outcome	100 (4/4)	0.9	0	N/A
108. Laboratory monitoring: antiepileptics	Process	– (0/0)	–	–	–
109. Duplications: drugs for topical use	Process	39 (12/31)	7	61	–16
110. Duplications: drugs from the same medication class	Process	29 (31/107)	23	71	1
Patient information					
111. Background information	Process	64 (294/457)	100	36	38***
112. Supplements or OTC medicines	Process	65 (299/457)	100	35	22***
113. Swallowing function	Process	49 (225/457)	100	51	36***
114. Laboratory monitoring: renal function	Process	28 (127/457)	100	72	5**

Continued

Table 1 Continued

No. Quality indicators by therapeutic area	Type	QI score (%) (numerator/ denominator)	Applicability (%)	Improvement potential (%)	Sensitivity to change (%)
115. Vaccination: influenza	Process	47 (216/457)	100	53	20***
116. Vaccination: pneumococcus	Process	35 (162/457)	100	65	12***
117. Medication administration	Process	64 (292/455)	100	36	22***
118. Transitional care	Process	56 (19/34)	7	44	0
119. Medication adherence: unused medicines	Process	43 (64/150)	33	57	13
120. Willingness to deprescribe	Process	32 (145/457)	100	68	13***
121. Medication administration: medication frequency	Outcome	53 (242/457)	100	47	2

Grey bars, QIs that met all threshold values.
*p<0.05; **p<0.01; ***p<0.001.
†QIs that did not meet the criteria of acceptability.
ACE inhibitors, angiotensin converting enzyme inhibitors; ADR, adverse drug reaction; ARBs, angiotensin II receptor blockers; BPSD, behavioural and psychological symptoms of dementia; CCBs, calcium channel blockers; ChEIs, cholinesterase inhibitors; COPD, chronic obstructive pulmonary disease; DOACs, direct oral anticoagulants; LABAs, long-acting beta-2 agonists; LAMAs, long-acting muscarinic antagonists; N/A, not applicable; NSAIDs, non-steroidal anti-inflammatory drugs; OTC medicines, over-the-counter medicines; PPIs, proton pump inhibitors; SGLT2 inhibitors, sodium-glucose cotransporter-2 inhibitors; SSRIs, selective serotonin reuptake inhibitors; TCAs, tricyclic antidepressants.

in the study protocol. During the meeting, one moderator (KF) explained the concept of measuring quality of care using QIs and another moderator (NS) provided information on the study protocol and the way of data collection. The video of the training session was provided to participants who were unable to attend in person, and this was supplemented by a series of online meetings via Zoom, to ensure that all participants had a good understanding of the study protocol.

Data collection

A web application platform (https://www.jp-quest2.com/) was developed by KF and NS for data reporting and data visualisation using Python V.3.7.6 (Python Software Foundation) and Django framework V.2.0.2 (Django Software Foundation). The community pharmacy study participants ('participants') could monitor their QI scores over time and compare them with data from other participants stratified by regional and national levels (figure 2). The patients of participants were eligible for inclusion if they were aged over 75 years and taking six or more prescription medicines for >4 weeks (polypharmacy). Patients who met the inclusion criteria were recruited by study participants. After informed consent was obtained from all participants and patients, deidentified prescription data and medication review reports, which were collected and recorded as part of routine consultation by community pharmacists were used as study data. There was no additional time or burden for patient involvement. During the study period, every time a pharmacist provided a dispensing service for a consented patient, the pharmacist self-reported values for each QI, both numerator and denominator, via the web application platform (figure 2) based on the information collected from the patients and information provided to the patients that were recorded in an electronic medication management system. The study participants were encouraged to report QIs for each patient once a month. Dichotomous variables with the values of 'yes' and 'no' were used to report each QI if patients met the criteria of QI in denominator.

Additionally, participants were encouraged to attend monthly online meetings throughout the study period to discuss practical issues with members of the research team. These meetings also provided opportunities to exchange practical advice on providing pharmacy services for patients with polypharmacy. Each meeting summary was sent to all participants. A mid-term meeting (17 October 2020) and a final meeting (14 March 2021) were also virtually conducted.

Measurement properties assessed

The following measurement properties of QIs were tested in this study.[23]

- Applicability: a QI was considered 'not applicable' if the number of patients in the denominator was <5% of the patients in all pharmacies at the final month.[24]
- Improvement potential: a QI was considered 'low improvement potential' if the QI score was ≥90% during the study period.[24–26]
- Acceptability: a QI was considered 'not acceptable' if the QI did not form an alignment with professional values and practice.[27]
- Implementation issues: full consequence of implementation of QIs (eg, unintended consequence, positive consequence, potential barriers or potential facilitators).[27 28]
- Sensitivity to change: a QI was considered 'not sensitive' if the difference between the QI scores at the first month and at the final month was not statistically significant.[27 29]

Self-report form

QI-1: A. Sedative hypnotics/anxiolytics, ADR monitoring: Benzodiazepines				
Denominator	Number of older people taking the following medications: ● Benzodiazepines	○ N/A		◉ Yes
Numerator	Number of those that were evaluated for ADRs (oversedation, cognitive decline, loss of motor function, falls, fractures)	○ N/A	○ No	◉ Yes
QI-2: A. Sedative hypnotics/anxiolytics, Guidance: Benzodiazepines				
Denominator	Number of older people taking the following medications: ● Benzodiazepines	○ N/A		◉ Yes
Numerator	Number of those who received information about a benzodiazepine withdrawal syndrome	○ N/A	◉ No	○ Yes

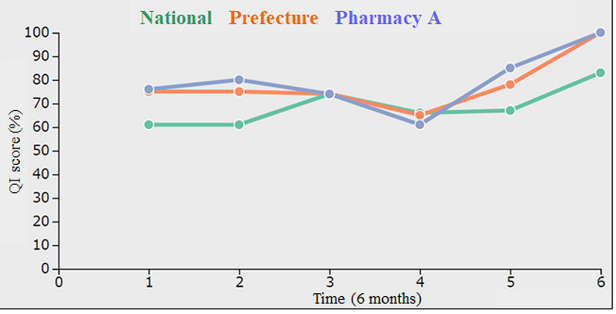
QI scores at national, regional and pharmacy level

QI-1: A. Sedative hypnotics/anxiolytics, ADR monitoring: Benzodiazepines

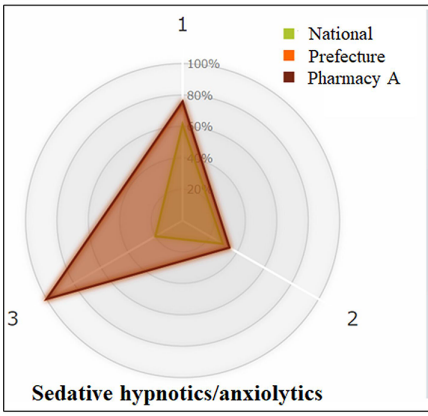
Definition	Percentage of those taking benzodiazepines whose ADRs were evaluated and recorded in the past 3 months
Numerator	Number of those that were evaluated for ADRs (oversedation, cognitive decline, loss of motor function, falls, fractures)
Denominator	Number of older people taking the following medications: ● Benzodiazepines

Number of patients (numerator/denominator)

	July 1st	August 2nd	September 3rd	October 4th	November 5th	December 6th
National	60 / 98	57 / 94	62 / 84	52 / 79	51 / 76	66 / 80
Prefecture	24 / 32	21 / 28	20 / 27	20 / 31	18 / 23	28 / 28
Pharmacy A	22 / 29	20 / 25	17 / 23	17 / 28	17 / 20	25 / 25



QI scores at disease level



QI	A. Sedative hypnotics/anxiolytics
1	Percentage of those taking benzodiazepines whose ADRs were evaluated
2	Percentage of those taking benzodiazepines who received information about a benzodiazepine withdrawal syndrome
3	Percentage of those taking the following medications, whose ADRs were evaluated ●Ramelteon & inhibitors of CYP1A2 ●Triazolam, alprazolam, brotizolam or suvorexant & inhibitors of CYP3A4

QI scores at patient level

ID	Age	Sex	July	August	September	October	November	December	Details
1	86	M	35% (6/17)	41% (7/17)	33% (5/15)	41% (7/17)	79% (15/19)	71% (12/17)	See details
2	92	F	35% (8/23)	36% (8/22)	45% (9/20)	50% (10/20)	0% (0/0)	83% (19/23)	See details
3	86	F	75% (15/20)	37% (7/19)	37% (7/19)	61% (11/18)	89% (17/19)	0% (0/0)	See details

Figure 2 Web application screen. Quality indicator (QI) scores are timely calculated when denominator and numerator of each QI item for patients are self-reported through the web application platform. Data visualisation can be used to monitor their own QI score, explore the trends and compare them with other participants' scores at a regional and national level. ADRs, adverse drug reactions.

Statistical analyses

Descriptive statistics for patient characteristics were summarised as means (SD), medians (IQR) or percentages, using Python. For sensitivity to change, since dichotomous variables were used in QIs the impact of quality improvement efforts on score changes during the study period was analysed using multilevel logistic regression in R V.3.6.1 (R Foundation), with community pharmacy modelled as a random effect and adjusting for patients' age and gender.[30] A two-sided p value of <0.05 was considered statistically significant. Analysis was conducted by principal researcher NS and all codes were verified by KF.

Qualitative interviews

Interview setting

After the observational study, in-depth semistructured online interviews were conducted to assess the acceptability of and any implementation issues with the set of QIs. If there were multiple pharmacist participants from one pharmacy, all were invited to a group interview to get a wider range of views about the implementation of QIs in their practice. Interview participants were purposively recruited by NS and KK based on location, ownership, employment status and the number of patients reported in the study, to maximise the depth, richness and scope of the range of views. A total of 26 pharmacists (10 community pharmacists, 9 pharmacy managers, 3 managers working at the head office and 4 owners) participated in the interviews (response rate 74%, 26/35) (see online supplemental appendix 2). Eight did not respond to an invitation (five pharmacy managers, one owner and two who did not complete QI report in the study) and one declined to participate (one pharmacy manager).

Interview data collection

All interviews were conducted by NS (a female pharmacist and researcher with training and experience in qualitative research) in Japanese via Zoom following a semistructured interview guide and audio-recorded with notes taken during interviews (see online supplemental appendix 3).[23] Interviews were continued until three consecutive interviews provided no additional themes (ie, data saturation).[31] Before ending each interview, interviewees were allowed to provide any further comments. The median interview time was 44 min (range 27–67 min). All interview data were deidentified and transcribed verbatim into Japanese.

Qualitative analysis

All interview data were thematically analysed and managed using NVivo V.12 Pro.[32] The first three interviews were coded independently by NS and KF (a male pharmacist and researcher trained in qualitative methods) and then identified themes were discussed to ensure the cording process by NS, KF and KK (a pharmacy academic with expertise in geriatric care). The remaining interviews were coded and analysed by NS. Data saturation was confirmed by NS, KF and KK.[31] The identified themes and narrative examples were transcribed into English by NS and then KF confirmed the translation. The interpretation of findings was reviewed by TFC (a senior researcher trained in qualitative methods).

Patient and public involvement

Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

RESULTS

Sixty pharmacies participated in the study. Of these, participants from 42 pharmacies in 10 different prefectures reported data about 457 patients (table 2). Participants from the remaining 18 pharmacies did not complete data and were excluded from analyses. The median age of patients was 82 years (IQR: 79–86) and 44% were men. In terms of the QI measurement properties, 53 QIs met the criteria of applicability, improvement potential, acceptability and implementation issues. Of these, 17 had a high sensitivity to change (table 1). Interviews with 26 pharmacists identified 8 overarching themes (see online supplemental appendix 4). Narratives are presented in table 3. The findings obtained from both quantitative and qualitative studies were triangulated and stratified by each measurement property.

In applicability, 58 of 121 QIs (48%) were considered 'applicable' (medicine-specific indicators 47/110, general indicators 11/11). In medicine-specific indicators, all QIs regarding antihypertensives, laxatives, anticholinergics met the criteria, while none of the QIs regarding antidepressants, antimycobacterials, drugs for behavioural and psychological symptoms of dementia and analgesics for cancer pain met the criteria. Some interviewees reported that low applicability of QIs reduced their willingness to participate in the project, saying that 'when a QI had a small number of patients in the denominator, the graph was fluctuating and not interesting at all (P7)'. On the other hand, regardless of the result of applicability, a comprehensive set of QIs for a specific disease was reported to give pharmacists an opportunity to expand their knowledge on geriatrics, saying that 'I liked that a large number of items (for some diseases) were included. Pharmacists should know all QI statements (P5)'.

Regarding improvement potential, the majority of QIs with high applicability (55/58) were considered as 'having improvement potential'. Three QIs (QIs 20, 22, 38) did not have room for improvement. Interviewees commented on the significance of identifying QIs with a low score, saying that 'I realised that the QI scores regarding medication review of α-blockers and sulfonylureas (ie, withdrawal of inappropriate medicines) should be improved (P17)'.

Most interviewees mentioned that all QIs were 'acceptable' both ethically and clinically. Particularly, participants were willing to accept general indicators, saying that 'I have never checked the vaccination status of my

Table 2 Characteristics of pharmacies and patients in a field testing

Pharmacies' characteristics (n=42)	n*
Pharmacy location	
Rural	14 (33)
Semiurban	12 (29)
Urban	16 (38)
Size of pharmacy	
Independent (1 pharmacy)	4 (10)
Small chain (2–9 pharmacies)	2 (5)
Medium chain (10–99 pharmacies)	32 (76)
Big chain (≥100 pharmacies)	4 (10)
Type of pharmacy	
Independent pharmacy	4 (10)
Pharmacy adjacent to a clinic	27 (64)
Pharmacy adjacent to a hospital	11 (26)
Pharmacist number in a pharmacy per day	
<3 pharmacists	14 (33)
3–5 pharmacists	16 (38)
>5 pharmacists	12 (29)
Patient number in a pharmacy per year	
<10 000 patients	7 (17)
10 000–19 999 patients	18 (43)
20 000–29 999 patients	9 (21)
≥30 000 patients	8 (19)
Patients' characteristics (n=457)	**n***
Gender	
Male	203 (44)
Female	254 (56)
Age, median (IQR)	82 (79–86)
Age group	
75–79	131 (29)
80–84	179 (39)
85–89	105 (23)
90–94	34 (7)
≥95	8 (2)
Location	
Rural	210 (46)
Semiurban	73 (16)
Urban	174 (38)
Number of visits to pharmacies, median (IQR)	4 (3–6)
Number of therapeutic categories, median (IQR)	4 (3–5)

*Values are presented as number (%) or median (IQR).

patients before. Now we check their vaccine status and recommend a flu shot if necessary (P22)'. On the other hand, a QI about the long-term use of non-steroidal anti-inflammatory drugs (NSAIDs) without gastroprotection (QIs 51, 52) was considered as 'not acceptable' by some participants, saying that 'I hesitate to recommend the clinician to prescribe an additional medicine to patients who are already taking a lot of medications regardless of the reason (P3)'.

Most of the implementation issues were in relation to workload, such as spending more time on counselling, documenting and learning QI statements. However, interviewees indicated that most problems could be addressed with system support. In the first month online discussion, one participant requested to create a web page where pharmacists could review results at the patient level, saying that 'I am keen on looking at the adherence rate of QI statements at patient level rather than aggregated scores at pharmacy or prefecture level'. In response to the request, a relevant web page was introduced from the second month of the study (figure 2).

For sensitivity to change, 53 of 121 QIs had good measurement properties and were included in a multilevel logistic analysis. The sensitivity to change was statistically significant for 17 QIs. The scores on most of the general indicators (8/11) improved during the study, while only 9% of medicine-specific indicators (9/42) improved. The QIs with high sensitivity to change were all process indicators. Some interviewees commented that the improvement of QI scores motivated them. On the other hand, other interviewees felt that their role as a pharmacist was limited by the fact that pharmacists' deprescribing recommendations were rarely accepted by physicians. The interview results also revealed that QIs requiring pharmacists' expertise were less likely to improve the scores. For example, a QI on the assessment of renal function (QI 114) showed a relatively low improvement of 5% because pharmacists hesitated to ask patients about their creatinine levels. One interviewee commented that 'I am not sure if I can provide my patients with proper advice based on their blood test results (P19)'. Furthermore, some interviewees reported the negative impact of asking more questions to patients trying to improve scores, which caused patients to worry about their health, saying that 'my patient told me 'was there something wrong?' when I asked her about her health and the blood test result. I might have asked too many questions to her (P9)'.

DISCUSSION

Validated QIs with established measurement properties are a well-recognised mechanism to measure healthcare quality.[21 33] This study assessed the measurement properties of a validated set of 121 face and content validated QIs for evaluating the impact of community pharmacists on geriatric pharmacotherapy in primary care in Japan. This QI set allowed pharmacists to identify potential areas of care which could be improved at the level of individual patient, pharmacist, pharmacy and healthcare system.

In general, the applicability of medicine-specific indicators is greatly influenced by the setting compared with

Table 3 Themes identified with narrative examples

Themes	Narrative examples
Indicator characteristics	Positive: 'I liked that a large number of items (for some diseases) were included. Pharmacists should know all QI statements'. (P5)
	Negative: 'My patients are well. I think it is not always necessary to measure QIs'. (P22)
	Barriers: 'I hesitate to recommend the clinician to prescribe an additional medicine to patients who are already taking a lot of medications regardless of the reason'. (P3)
	Facilitators: 'I realised that once I became familiar with QI statements, I was able to check QIs so efficiently. I think continuity is a key to success'. (P4)
Web application	Positive: 'The application was easy to use and access the data'. (P7)
	Negative: 'When a QI had a small number of patients in the denominator, the graph was fluctuating and not interesting at all'. (P7)
	Barriers: 'There were visualisations that I did not understand. However, those were not important for me because I was only interested in my pharmacy score'. (P2)
	Facilitators: 'It would be nice if the application was a bit simpler and linked to pharmacy record system so that we work efficiently'. (P23)
Policy	Negative: 'One of my achievements in this project was that my patient stopped routinely taking a pain killer. But I was disappointed with the current policy because my service was not adjusted to financial incentives'. (P3)
	Barriers: 'I first worked hard on the QI project. But I realized that there was no financial merit to our pharmacy'. (P1)
	Facilitators: 'I want policymakers or pharmacist's organizations to use QIs to increase transparency and accountability about our services. I guess that QIs might be adjusted to local policy as well'. (P18)
Patient	Positive: 'By spending more time on patient counselling, my patient remembers my name. She is now happy to talk to me about their condition and lifestyle'. (P2)
	Negative: 'my patient told me 'was there something wrong?' when I asked her about her health and the blood test result. I might have asked too many questions to her'. (P9)
	Barriers: 'When I ask patients themselves, sometimes they do not know even know how they feel. I need to talk to their family or carers, but not always a success'. (P15)
	Facilitators: 'My patients have sufficient education on warfarin therapy (I educated them). They usually show their international normalised ratio (INR) values to me after INR testing was performed by their doctors'. (P10)
Time	Negative: 'I spent a lot of time on patient counselling to explain deprescribing more than I thought. It was frustrating'. (P9)
	Barriers: 'I think that time is the critical issue. I was being asked to spend more time on the patients' counselling and report QI items in addition to a regular workload'. (P23)
	Facilitators: 'Pharmacists participated in the QI project, but now I realised that all staff, such as registered dieticians and pharmacy staff, should have worked. I think they are capable of reporting QI items and information they have is sometimes important to understand patients'. (P15)
Competence	Positive: 'I have never checked the vaccination status of my patients before. Now we check their vaccine status and recommend a flu shot if necessary'. (P22)
	Negative: 'That was boring because QI score was rarely changed'. (P16)
	Barriers: 'I am not sure if I can provide my patients with proper advice based on their blood test result'. (P19)
	Facilitators: 'There are opportunities to learn pharmacotherapy for pharmacists, but those do not focus on guidelines'. (P21)
Pharmacy administration	Positive: 'I was worried about my staff before. According to QI score, my staff were working well, so I was happy to see their work using QIs'. (P18)
	Negative: 'I felt more responsibility for improving the score as a manager'. (P25)
	Barriers: 'As a manager, I wanted to discuss QI score with my staff. But I hesitated to do so because they were always busy'. (P24)
	Facilitators: 'I think it would be different if we had a quality control expert in our pharmacy'. (P21)
Collaboration	Positive: 'I liked that we (care manager and I) work together to detect PIMs'. (P1)
	Negative: 'Doctor did not accept my recommendation of changing sulfonylureas because following the medication guideline or guidance was not mandatory'. (P4)
	Barriers: 'When we communicate with doctors in the hospital, we usually make online reports to suggest PIMs. But the clinics do not have such a convenient system. We have to make a call, which is time-consuming'. (P26)
	Facilitators: 'I think pharmacists should actively collaborate with care managers in addition to doctors. I know some patients who do not have home care, but they start to communicate with care managers'. (P1)

Each theme is presented with indicative verbatim quotes from participants, anonymised by alphanumeric codes (eg, P1=Pharmacist 1).

the general indicators.[34] In this study, the QIs for antihypertensives and antidiabetics had higher applicability than those for antidepressants and antifungals, which was consistent with their morbidity in Japan.[35] Considering that some interviewees reported that the use of QI with low applicability may demotivate pharmacists to monitor the quality of care using QI scores, it may be important to focus on QIs for diseases with high prevalence. However, when QIs were used at the patient level, each QI was equally important regardless of their overall applicability, to ensure a comprehensive assessment of care quality.

The study also revealed that the majority of QIs (95%) had room for improvement. A previous validation study on QIs for pharmacist home visit services showed that 73% of the QI set (29/40) had room for improvement, indicating that the quality of home healthcare services might be higher than the quality of geriatric primary care.[23] In fact, a previous study reported that home care allows for a deeper relationship with the patient than outpatient care, and as a result, higher quality of care could be provided.[36] Given the transition of older people from primary care to home care, it is important to longitudinally evaluate quality of care for them using both QIs.

Assessing the acceptability of QIs is important from the perspective of both the person being assessed (the patient) and the person conducting the assessment (the healthcare professional).[37] While dispensing gastroprotective agents to patients on long-term use of NSAIDs (QIs 51, 52) is evidence based, adding further medication to patients with polypharmacy was not accepted by some participants. This issue may be specific to care for patients with polypharmacy, indicating the importance of assessing acceptability, even when the content is evidence-based QIs.[38]

In terms of the implementation issues, most findings in this study aligned with those reported in other countries. For example, it is known that use of QIs increases workload[23 27] and that some may be questioned the 'credibility' of QIs.[39] Furthermore, improving QI scores may require additional interpersonal and professional skills,[23 39] including interprofessional communication. These factors may explain why 18 of 60 community pharmacies did not complete the study. One unique facilitator identified in this study was the involvement of pharmacy staff (counter staff and registered dietitians), indicating that all pharmacy staff members are required to work together to improve the quality of care on an ongoing basis. In addition, it is important to note that participants placed more importance on compliance with QI statements at the patient level, rather than QI scores at the pharmacy or other levels. We therefore increased the functionality of the web application to enable community pharmacists to identify patient level data and hence identify areas for intervention (figure 2). Further study is needed to evaluate the impact of the use of the QIs on patient clinical outcomes and health service provision and planning.

QIs should be able to detect changes in the quality of care. Kondo *et al* reported that a problem in community pharmacists' implementation of dose adjustment based on renal function for older people was the lack of information on patients' renal function,[40] which was consistent with our study. The present study also showed that some pharmacists do not intentionally ask patients about their laboratory test results (ie, creatinine levels) because they do not know how to respond based on the results. Therefore, in addition to the use of QIs, educational programmes on the effect of decreased renal function on the dosage of drugs excreted by kidneys may be required.

We acknowledge that this study has some strengths and limitations. One strength was that this was the first to validate a comprehensive set of QIs for geriatric pharmacotherapy across seventeen different disease states in patients with polypharmacy. Although QIs have been developed over the decades, few QI studies have covered multiple disease states and been field tested to establish their measurement properties.[41] We strongly believed that multidimensional assessment is required for geriatric patients, in addition to disease state focused assessment.[42 43] Another strength was the multistep, mixed methods process for the evaluation of the measurement properties of the QIs. Our relatively small sample size was a limitation. To minimise this, community pharmacies were purposively recruited from across Japan to include diversity concerning location and ownership. Moreover, QI data were self-reported by participants, which might have contributed to a reporting bias. If QI scores were automatically calculated and monitored without any additional workload on healthcare professionals, this could eliminate this bias. In addition, the QIs evaluated were based on Japanese national guidelines and guidance documents for geriatric patients and we acknowledge that this may vary in other countries.[14 15] However, we believed that the QIs may be applicable to other countries as the concept and challenges for geriatric pharmacotherapy are similar.

CONCLUSION

The face and content validated 121 QIs for medication safety in geriatric pharmacotherapy were tested for their 5 measurement properties. This QI set can be used to identify patients who may benefit from further assessment of their medication regimen. If applied, the QIs can facilitate the prioritisation of care provided by community pharmacists, both in general terms and for specific disease states. Further mechanisms to automatically collect and report data should be established to facilitate sustainable quality improvement initiatives. Future studies should assess the impact of quality improvement activities as measured by QIs on patients' clinical, humanistic and economic outcomes, at different levels within healthcare systems.

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ORCID iDs
Noriko Sato http://orcid.org/0000-0003-0106-8376
Kenji Fujita http://orcid.org/0000-0001-7876-6004
Hiroshi Okada http://orcid.org/0000-0001-5208-9383
Timothy F Chen http://orcid.org/0000-0003-4189-8403

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