A survey of the views and capabilities of community pharmacists in Western Australia regarding the rescheduling of selected oral antibiotics in a framework of pharmacist prescribing

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Background: Antibiotic misuse in the community contributes to antimicrobial resistance. One way to address this may be by better utilizing community pharmacists' skills in antibiotic prescribing. The aims of this study were to examine the level of support for "down-scheduling" selected antibiotics and to evaluate factors determining the appropriateness of community pharmacist prescribing for a limited range of infections, including their decision to refer to a doctor.

Methods: Self-administered questionnaires, including graded case vignette scenarios simulating real practice, were sent to Western Australian community pharmacists. In addition to descriptive statistics and chi-square testing, a General Estimating Equation (GEE) was used to identify factors associated with appropriateness of therapy and the decision to refer, for each of the seven vignettes.

Results: Of the 240 pharmacists surveyed, 90 (37.5%) responded, yielding 630 responses to seven different case vignettes. There was more than 60% respondent support for expanded prescribing (rescheduling) of commonly prescribed antibiotics. Overall 426/630 (67.6%) of the responses chose to treat the patient while the remaining 204/630 (32.4%) referred the patient to a doctor. Of those electing to treat, 380/426 (89.2%) opted to use oral antibiotics, with 293/380 (77.2%) treating with an appropriate selection and regimen. The GEE model indicated that pharmacists were more likely to prescribe inappropriately for conditions such as otitis media (p =0.0060) and urinary tract infection in pregnancy (p <0.0001) compared to more complex conditions. Over 80% of all pharmacists would refer the patient to a doctor following no improvement within 3 days, or within 24 hours in the case of community acquired pneumonia. It was more common for younger pharmacists to refer the patient to a doctor (p=0.0165).

Discussion: This study adds further insight into community pharmacy/pharmacist characteristics associated with appropriateness of oral antibiotic selection and the decision to refer to doctors. These findings require consideration in designing pharmacist over-the-counter prescribing models for oral antibiotics.

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30   **Abstract**

31   **Background:** Antibiotic misuse in the community contributes to antimicrobial resistance. One

32   way to address this may be by better utilizing community pharmacists' skills in antibiotic

33   prescribing. The aims of this study were to examine the level of support for "down-scheduling"

34   selected antibiotics and to evaluate factors determining the appropriateness of community

35   pharmacist prescribing for a limited range of infections, including their decision to refer to a

36   doctor.

37   **Methods:** Self-administered questionnaires, including graded case vignette scenarios simulating

38   real practice, were sent to Western Australian community pharmacists. In addition to descriptive

39   statistics and chi-square testing, a General Estimating Equation (GEE) was used to identify

40   factors associated with appropriateness of therapy and the decision to refer, for each of the seven

41   vignettes.

42   **Results:** Of the 240 pharmacists surveyed, 90 (37.5%) responded, yielding 630 responses to

43   seven different case vignettes. There was more than 60% respondent support for expanded

44   prescribing (rescheduling) of commonly prescribed antibiotics. Overall 426/630 (67.6%) of the

45   responses chose to treat the patient while the remaining 204/630 (32.4%) referred the patient to a

46   doctor. Of those electing to treat, 380/426 (89.2%) opted to use oral antibiotics, with 293/380

47   (77.2%) treating with an appropriate selection and regimen. The GEE model indicated that

48   pharmacists were more likely to prescribe inappropriately for conditions such as otitis media

49   ($p=0.0060$) and urinary tract infection in pregnancy ($p<0.0001$) compared to more complex

50   conditions. Over 80% of all pharmacists would refer the patient to a doctor following no

51   improvement within 3 days, or within 24 hours in the case of community acquired pneumonia. It

52   was more common for younger pharmacists to refer the patient to a doctor ($p=0.0165$).

53   **Discussion:** This study adds further insight into community pharmacy/pharmacist characteristics

54   associated with appropriateness of oral antibiotic selection and the decision to refer to doctors.

55   These findings require consideration in designing pharmacist over-the-counter prescribing

56   models for oral antibiotics.

57

58 **Introduction**

59 Over the last twenty five to thirty years, a number of countries including New Zealand (NZ),

60 United States of America (USA), United Kingdom (UK), the Netherlands, Japan and Australia,

61 have reclassified or switched several drugs with an established safety profile from prescription to

62 non-prescription availability. [1, 2]. In Australia, examples of drugs that have been reclassified

63 include emergency hormonal contraception, the oral azole antifungal fluconazole and proton

64 pump inhibitors. [1] In NZ and the UK, the antibiotics trimethoprim and azithromycin

65 respectively, may also be supplied by suitably trained pharmacists. [3, 4] As antibiotic resistance

66 has been declared a global threat by the World Health Organization (WHO) [5], employing

67 pharmacists' knowledge and expertise in the appropriate selection and use of reclassified

68 antibiotics could potentially help reduce the level of inappropriate antibiotic use and therefore

69 resistance. [6] Antimicrobial agents available under strict protocols from suitably qualified

70 pharmacists to maintain antimicrobial stewardship could improve patient access to immediate

71 treatment and reduce the workload of general practitioners (GPs). [4, 6, 7] Widespread

72 inappropriate use of antibiotics in hospitals and the community has led to the development of a

73 specialist antibiotic pharmacist's role in the UK. [8] In a study in the community pharmacy

74 setting, researchers in the USA investigated the use of rapid point-of-care tests by pharmacists to

75 allow clinical decision making so that appropriate treatment could be initiated for patients with

76 influenza or group A *Streptococcus* (GAS) pharyngitis. Researchers reported that this innovative

77 physician-pharmacist disease management program produced positive progress toward reducing

78 the inappropriate use of antibiotics. [9]

79

80   Pharmacists are reported to adhere to prescribing guidelines [10] and improve patients' access to

81   medicines. [11] In Australia, the current framework administering access to medicines includes

82   "down-scheduling" and selected medicines previously restricted to 'Prescription only' or

83   'Schedule 4 (S4)' have been reclassified as 'Pharmacist only' or 'Schedule 3 (S3)' medicines,

84   thereby allowing them to be provided over-the-counter (OTC).[2] It is a requirement in Australia

85   that S3 medicines are provided by a pharmacist or under the direct supervision of a

86   pharmacist.[12] In 2010, chloramphenicol ophthalmic products were reclassified from S4 to S3

87   thereby expanding the options and capability of Australian pharmacists treating acute bacterial

88   conjunctivitis and providing improved community access to an effective antibiotic treatment.

89   Similar rescheduling decisions had been made in the UK and New Zealand in previous years.

90   [13]

91

92   The roles of community and hospital pharmacists have been extended to include prescribing, in

93   several countries including Canada [14, 15], the USA [16], NZ and the UK, where pharmacists

94   are working within various prescribing models, including: collaborative, supplementary and

95   independent pharmacist prescribing.[17] In Australia, expanding the pharmacist's prescribing

96   role is still under review. [18-22] Currently, a range of Schedule 2 (S2) drugs which are only

97   available from pharmacies (Pharmacy only) and S3 drugs which require the direct involvement

98   of a pharmacist (Pharmacist only), are available from community pharmacies for minor or self-

99   limiting conditions. [19, 23, 24]. A number of protocols are in place on selected 'Pharmacist

100   only' medicines such as prescribing emergency contraception. [12] Access to selected antibiotics

101   via a protocol could enable community pharmacists to effectively treat a range of infections. [19,

102   23, 24]

103

104   There are additional factors in the health system in Australia that influence patient access to

105   antibiotics. A repeat prescribing model is part of the Pharmaceutical Benefits Scheme in

106   Australia, whereby a medical practitioner can order repeats for antibiotics initially prescribed by

107   them. The repeat antibiotic prescription is intended to be obtained in case the patient/ client does

108   not adequately improve following the initial course of antibiotics, or a relapse of the same

109   symptoms subsequently occurs. These repeat prescriptions are valid within a period of 12 months

110   following the initial prescription. [25] This may lead to misuse of antibiotics in patients/ clients

111   with repeat prescriptions that choose to self-diagnose and self-manage their symptoms. To

112   address this issue, expanding pharmacists' role in antibiotic prescribing has been suggested. [25]

113

114   Given that much of the existing literature has explored pharmacists' views on expanding their

115   prescribing role [17, 19, 21] and support has been given for pharmacist prescribing for a limited

116   range of infections, there is a need for research aimed at assessing pharmacists' perceptions

117   when confronted with various real life scenarios of antibiotic prescribing. [17, 19-21, 26] This

118   would provide valuable insight to policymakers in relation to designing a model of pharmacist

119   prescribing of antibiotics for a limited range of infections in the community setting. This study

120   therefore aims to explore factors determining the appropriateness of community pharmacist

121   prescribing for a limited range of infections, including their decision to refer to a doctor and

122   examine the level of support for "down-scheduling" selected antibiotics.

123

124   **Materials and Methods**

125 This cross-sectional quantitative study involved a postal survey of practising rural and
126 metropolitan community pharmacists in Western Australia (WA). Questions included seven case
127 vignettes which were used due to their ability to simulate key features of a range of 'real-life'
128 scenarios. [27, 28] They were chosen because they carried the external validity strengths of
129 quantitative-survey based research as well as the internal validity strengths of experimental
130 methods. [27, 28] A review of the literature informed the design of the questionnaire [13, 27,
131 28], while the medical conditions shown by scenarios in the vignettes were based on literature
132 and by using the Australian Therapeutic Guidelines (ATG) for antibiotics. [27, 29] The
133 questionnaire and vignettes, which were developed by the researchers, were piloted by six
134 community pharmacists, some with extensive antibiotic experience, for face and content validity
135 and their feedback was used to improve the questionnaire and vignettes.

136

137 The sections of the questionnaire were: (A) demographic information; (B) statements of views
138 on expanding the pharmacist's role in prescribing antibiotics and Section (C) included the case
139 vignettes.

140

141 **Case vignettes**

142 The case vignettes consisted of seven scenarios and the respondents were asked for their
143 preferred treatment option, under the hypothetical assumption that they were permitted to
144 prescribe oral antibiotics. The design of the case vignettes was such that the final diagnosis was
145 evident. The scenarios included consideration to some of the key features of case-vignette design
146 i.e. experimental aspect (various antibiotic based scenarios and their effect on respondent's
147 choice of treatment); controlled aspect (i.e. same pharmacists responding to different scenarios)

148   and contextual aspect as demonstrated by variability within each of the scenarios allowing for the

149   verisimilitude of the scenario. [27] The respondents were asked to select an option from: refer to

150   a GP, treat with oral antibiotics (from a list), or choose a different treatment regimen. The list

151   included antibiotic regimens recommended in the ATG Antibiotics. [27, 29] The vignettes were

152   graded according to disease complexity. In cases where the selected management option was not

153   to refer to a GP, the respondent was asked what action they would take if there was no

154   improvement following 24 hours (community acquired pneumonia (CAP) or 3 days (other

155   vignettes).

156

157   **Questionnaire distribution**

158   The sampling frame was the list of 434 metropolitan and 164 regional community pharmacies

159   available from The Pharmacy Registration Authority of WA. A 40% sample was randomly

160   selected using a web based randomizer. Hospital pharmacies in WA were excluded. The final

161   questionnaire was distributed to 66 regional and 174 metropolitan community pharmacies in WA

162   in March 2015 and coded to be able to identify non-respondents. A cover letter explaining the

163   objectives and importance of the study was addressed to the 'manager/proprietor' and enclosed

164   with the questionnaires, information sheet and a reply paid envelope. Reminder letters

165   accompanied by additional questionnaires and reply paid envelopes were sent to non-responders

166   in April 2015.

167

168   **Sample size determination**

169   A sample size of 96 was considered the minimum necessary to conduct the inferential statistics

170   to identify independent variables exhibiting a moderate effect size, with 80% power and using

171   α=0.05[30]. With an anticipated 40% response rate based on previous studies [13], 240

172   pharmacies were invited to participate in the study, with the numbers of metropolitan and

173   regional pharmacies in line with the proportions of these in the sample frame (metropolitan

174   community pharmacies made up 72.5% and regional community pharmacies 27.5%).

175

176

177   **Data analysis**

178   Descriptive statistics (frequencies and percentages) were used to summarize the demographic

179   profile of participants, and their responses. Responses on a five point Likert scale (i.e. strongly

180   agree, agree, neutral, disagree and strongly disagree) were collapsed to a three point Likert scale

181   (agree, neutral and disagree), for the purpose of analysis.

182

183   *Analysis of level of support for expanded prescribing*

184   A composite score representing the respondents' overall attitude towards down-scheduling was

185   obtained as the mean of the first seven statements assessing different aspects of the respondents'

186   support for the down scheduling. The remaining two statements (relating to the design of the

187   pharmacy, and whether OTC oral antibiotics would increase resistance to antibiotics) were not

188   considered to be either supportive or unsupportive of down-scheduling, and therefore not

189   included in the calculation of the overall attitude score. Being a mean of responses on a 1-5

190   scale, the composite score could be interpreted on a similar scale. Therefore, the overall

191   response was classified as "in agreement" if the composite score was between 1 and 2

192   (inclusive), and classified as "not in agreement" otherwise. If the composite score was "in

193   agreement", then the respondent was classified as "supporting rescheduling", and not in support

194 of rescheduling if the score was "not in agreement". This variable was the primary outcome for

195 the analyses. A logistic regression model was used to identify any demographic variables

196 showing an association with this dichotomous variable. A backwards elimination strategy was

197 used to find the 'optimal' model. In this approach, all the independent variables were initially

198 included in the model, then the least significant was dropped, one at a time, until all variables

199 remaining in the model were significantly associated with the outcome.

200

201 ***Analysis of vignettes***

202 Analysis of factors associated with the choice to refer the patients depicted in the case vignettes

203 to their GP was analysed using a Generalised Estimating Equation (GEE). This model takes into

204 account the correlation between vignette responses made by the same respondent (using an

205 exchangeable correlation matrix structure). Inclusion of the vignette number as a factor in the

206 model allowed a comparison of the referral rates between vignettes. The same model was used to

207 identify factors associated with the appropriate oral antibiotic therapy selected for each vignette,

208 except that cases where the respondent elected to refer straight to the GP were excluded from this

209 analysis. Similarly to the logistic regression model above, a backward elimination strategy was

210 used when fitting the GEE model. The final results are expressed as adjusted odds ratios, their

211 95% confidence intervals, and p-values.

212

213 A p-value <0.05 indicated a statistically significant association. The statistical analyses were

214 performed using the SAS$^{©}$ version 9.2 software.

215

216   This study was approved by the Human Research Ethics Committee of Curtin University

217   (Approval Number RDHS-04-15).

218

219   **Results**

220   Of the 240 questionnaires distributed (66 regional and 174 metropolitan), 90 were returned. Of

221   these, 67/90 (74.4%) were from metropolitan and 23/90 (25.6%) regional community

222   pharmacists. The response rates from metropolitan community pharmacists (67/174; 38.5%) and

223   rural community pharmacists (23/66; 34.8%) were similar, leading to an overall response rate of

224   37.5% (90/240).   Medium sized (based on turn-over of AUD$1m to $2m) community

225   pharmacies were the largest cohort (38/89; 42.7%) (Table 1). Most pharmacists were in the age

226   categories 31-40 years (32/89; 36.0%) and 21-30 years (31/89; 34.8%). It is evident (Table 1)

227   that the overall number of respondents supporting the down-scheduling of selected oral

228   antibiotics (as defined by the "composite was 55.6% (50/90) which was independent of a wide

229   range of demographic pharmacy and pharmacist characteristics.

230

231

232   <Insert Table 1 here>

233
234

235

236   **Respondents' level of support for an expanded prescribing role for oral antibiotics**

237   With respect to pharmacist's views on "down-scheduling" of selected antibiotics, respondents

238   strongly supported statements regarding: the use of their skills and knowledge (70/90; 77.8%),

239   recognition by pharmacy clients (72/89; 80.9%) and treating of patients in a timely manner

240   (72/90; 80.0%), as illustrated in Figure 1.

241

242   <Insert Figure 1 here>

243

244   Results from fitting the logistic regression model showed that no variables were significantly

245   associated with the attitude towards rescheduling. The results indicate that approximately half of

246   the respondents favoured down scheduling regardless of any demographic variables such as their

247   gender, age, or experience. This supports the univariate associations shown in Table 1. A total of

248   50/89 pharmacists (i.e. 56.2 %) estimated that on average 10 or more patients per week would

249   seek advice for conditions where the pharmacist's best option would be to prescribe oral

250   antibiotics, suggesting that they face these situations on daily basis.

251   The two statements which were excluded from calculation of the 'level of support for down-

252   scheduling' score are included in Figure 1. These show that the current layout of 69/90 (76.7%)

253   of pharmacies would be conducive to diagnosis of infections and prescribing of antibiotics. Only

254   9/90 (10%) of respondents disagreed with the statement that provision of OTC oral antibiotics

255   could increase resistance to antibiotics, with the majority (65/90; 72.2%) agreeing with this

256   statement and the remaining 16/90 (17.8%) giving a neutral response.

257

258   **Respondents' level of support for community pharmacist prescribing selected oral**

259   **antibiotics**

260   More   than   60%   of   respondents'   (Figure   2)   supported   expanded   prescribing   of

261   phenoxymethylpenicillin   (56/90),   amoxicillin   with   clavulanic   acid   (55/88),   flucloxacillin

262   (61/88), cefalexin (64/90), amoxicillin (66/90) with 70/90 (77.9 %) supporting trimethoprim.

263   Few respondents supported rifampicin (2/87; 2.3%).

264   <Insert Figure 2 here>

265

266   **Case vignette scenarios**

267

268   A total of 630 vignette responses were received from the 90 respondents (7 vignettes per

269   questionnaire). Overall, responses to 426/630 (67.6%) of the vignettes were to treat the patient at

270   presentation compared to the remaining 204/630 (32.4%) where referral to the GP was the

271   preferred option. Of those who opted to treat, 380/426 (89.2%) chose to prescribe an oral

272   antibiotic, with 334/380 (87.9%) of them selecting an appropriate antibiotic regimen. The

273   decision to immediately treat was 80/90 (88.9%) for tonsillitis and 77/90 (85.6%) for otitis

274   media. The level of immediate treatment was much lower for acute pyelonephritis 44/90

275   (48.9%). The GEE model to identify factors associated with the decision to refer the patient to

276   their GP was based on all 630 responses to the case vignettes. Due to the large number of

277   variables in the model, only pairwise interaction terms which would be expected to be correlated

278   with each other were assessed for statistical significance (none was eventually included). Table 2

279   shows the full results of the GEE analysis. These data show that referral rates were similar for

280   acute pyelonephritis, chlamydial urethritis and urinary tract infections (UTI) in pregnancy.

281

282

283   <Insert Table 2 here>

284
285
286

287

288   The difference in choosing to refer between pharmacists of different gender was small (male

289   33.5% vs female 31.2%) but statistically significant (*p*=0.0198), with male pharmacists more

290   likely to refer compared to female pharmacists. In addition, the older respondents were less

291   likely to refer patients (*p*=0.0165). Respondents from small turnover pharmacies (*p*=0.0122)

292   were more likely to refer than those from large turnover pharmacies; those who expected only a

293   low number of patients to be seeking advice were more likely to refer, pharmacists with fewer

294   patients treated at their pharmacy where oral antibiotics would be beneficial (<4 per week,

295   p=0.0205) and those respondents who were generally not in favour of expanding pharmacists

296   prescribing role in antibiotics were also more likely to refer (Table 2).

297

298   **a) Appropriateness of therapy selected by vignette respondents**

299   A second GEE model was used to identify factors associated with an appropriate choice of

300   antibiotic.   This analysis used only the records where the respondent chose to immediately

301   prescribe oral antibiotics (426 records). The final model (following the backwards elimination

302   procedure) is shown in Table 3.

303
304

305   <Insert Table 3 here>

306

307

308

309   The reference category for comparing the different vignettes was the case of acute

310   pyelonephritis, which had the highest rate of appropriate antibiotic use (95.5%). Compared with

311   this group, antibiotics for otitis media (p=0.0060), UTI in pregnancy (p<0.0001) and CAP

312   (p=0.0283) were significantly less appropriately prescribed. The appropriateness of prescribing

313   for tonsillitis (p=0.5146), chlamydial urethritis (p=0.1337) and mild early cellulitis (p=0.8528)

314   were similarly appropriate to that for acute pyelonephritis (Figure 3)

315

316   Older respondents (>50 years) were less likely to prescribe appropriately (70.8% vs 78.9%;

317   p=0.02). Similarly, respondents who were working in the role of a consultant pharmacist (only 3

318   respondents, responding to 13 vignettes), were less likely to prescribe appropriately compared to

319   respondents holding other positions in the pharmacy (69.2% vs 77.5%; p=0.0068).

320

321   <Insert Figure 3 here>

322

323   **b) Respondents' decision making following no improvement on initial therapy**

324   Following three days of no improvement on initial therapy or 24 hours for CAP (excluding

325   immediate referrals to GP), most respondents would refer the patient to a GP for all vignettes

326   (Figure 4) compared to selecting a different antibiotic, increasing the dose of the current

327   antibiotic, using some alternative treatment or 'other'. For those who did not elect to refer to GP

328   at this later stage, the most common choice was to select another antibiotic, in particular for otitis

329   media (n=12/14; 85.7%), CAP (n=6/11; 54.5%) and UTI in pregnancy (n=3/3; 100%) compared

330   to other vignettes. In the case of CAP, respondents were asked to select therapy after 24 hours of

331   no improvement instead of 3 days. [29]

332

333   <Insert Figure 4 here>

334

335

336

337 **Discussion**

338 In the hypothetical situation that community pharmacists were permitted to prescribe OTC a

339 range of antibiotics, this study reports their intended antibiotic prescribing behaviour when faced

340 with scenarios simulating real practice. This study therefore provides a detailed insight into the

341 appropriateness of their choice of prescribing for a graded range of infections, and identifies

342 factors associated with appropriate prescribing. In addition it identifies medical conditions where

343 the pharmacist would generally choose to refer the patient to their GP on initial presentation in

344 the pharmacy, as well as following no symptom improvement. Acute pyelonephritis, chlamydial

345 urethritis and UTI in pregnancy were significantly less likely to be treated by a community

346 pharmacist than the other conditions presented.

347

348 In addition to findings suggesting a high level of appropriateness of antibiotic prescribing by

349 pharmacists (334/380; 87.9%), this study also confirmed the existing literature indicating that

350 pharmacists are supportive of an expanded prescribing role for a limited range of infections and

351 antibiotics. [19, 21] In this regard, pharmacists suggested a stronger preference for prescribing

352 trimethoprim, amoxicillin and cefalexin and little support was suggested for prescribing

353 antibiotics such as rifampicin and ciprofloxacin. Pharmacists also indicated higher confidence in

354 the treatment of less complicated infections. This is consistent with findings from previous

355 Australian studies. [19-21] Notably, trimethoprim has been prescribed OTC in Scotland using a

356 strict protocol providing improved patient access. [6]

357

358   In their responses to the case scenarios provided, most pharmacists would refer patients

359   following three days of no improvement on initial therapy (or following 24 hours in the CAP

360   case). This further supports the notion that community pharmacists are able to make decisions to

361   treat minor uncomplicated infections without treatment delays and appropriately refer to the GP

362   where complications arise. Minor ailments are reported to account for 10-20% of a doctors'

363   workload [31] with doctors showing support for the diversion of management of minor ailments

364   to non-medical prescribers including pharmacists. [32, 33]

365

366   In a majority (426/630; 67.6%) of the vignette responses in this study, the pharmacist opted to

367   treat patients compared to referring them to the GP from the outset. As demonstrated in

368   international studies [10, 14], this level of responses to treat selected patient scenarios may

369   suggest that community pharmacists are willing to manage a range of self-limiting infections. In

370   addition, a large number of pharmacists followed the recommended guidelines leading to

371   appropriate antibiotic therapy and potentially reduced antibiotic resistance. [5] An advantage of

372   antibiotic management is immediate patient access. However, it is noteworthy that when

373   mupirocin was reclassified OTC in NZ an increased resistance occurred in part from it being

374   made available from pharmacies. [34] However, similar levels of resistance were recorded in

375   WA where it was only available on prescription. [34]

376

377   It was found that pharmacists in this study who estimated that less than three patients per week

378   would seek their treatment advice, were more likely to refer patients to the GP. A study in Spain

379   reported that the number of hours worked and high patient numbers were associated with

380 generating more prescriptions by community pharmacists, concluding that longer work hours

381 was related to the pharmacist's understanding of their work. [35] This is consistent with the

382 present study where pharmacists from small turnover pharmacies were more likely to refer

383 patients to the GP compared to large turnover pharmacies. This may indicate a more

384 conservative approach to patient management than perceived by pharmacists in larger

385 pharmacies. A study of community pharmacists in WA revealed that pharmacies with a large

386 turnover were more supportive of the reclassification of chloramphenicol ophthalmic products

387 than small and medium sized pharmacies [13]. An explanation for this may be stronger

388 commercial interests for large pharmacies. Protocols would be essential to ensure antibiotic

389 stewardship if selected antibiotics were reclassified.

390

391 Older respondents (> 51 years) were less likely to refer patients to the GP and of those who

392 chose to treat the patient directly these older respondents were less likely to prescribe

393 appropriately. Caamaño at al. suggested that the more experienced pharmacists generated fewer

394 prescriptions and were more likely to refer a patient to their GP. [35] These findings are

395 supported by other studies where younger pharmacists were reported to place more importance

396 on the patient's and pharmacist's autonomy compared to older pharmacists, describing older

397 pharmacists as being 'more traditional' in their roles as pharmacists. [36, 37] Another

398 explanation may be the emphasis of education for older pharmacists would have been much less

399 patient centred. [38]

400

401 With a response rate of 37.5%, it is likely that some non-responders may have views on

402 pharmacists' expanded prescribing of selected oral antibiotics which may differ from those based

403   on the survey responders. However, with the high and consistent support for statements of views

404   on prescribing oral antibiotics, high level of pharmacists' willingness to treat the patients in

405   preference to GP referral, and overall high level of appropriateness of therapy selected, it is less

406   likely that non-respondents' responses would have significantly influenced the findings.

407   Furthermore, the wide range of conditions portrayed in the seven vignettes strengthens the

408   validity of the data. Case vignettes are often used to assess clinician's decision making behaviour

409   and judgements. [27] It should be highlighted that the literature suggests that this method

410   provides predictive behaviour in circumstances appropriated by the vignette, [27] thus the

411   vignettes provide a demonstration of potential performance. A limitation of the vignettes is that

412   although face and content validity of the vignettes were determined, the grading scale was not

413   specifically validated and therefore the reliability of the grading scale is not known.

414

415   This study demonstrated with the current framework of drug regulation that a "down-scheduling"

416   option could be utilised to enable improved access for the public to a limited range of antibiotics

417   for specific infections. This would also partially address the underutilisation of pharmacist's

418   skills and their high accessibility. Appropriate methods would need to be developed for this to

419   occur. [7]

420

421   Findings of this study should also be interpreted in context of the need to identify strategies and

422   protocols that minimise antibiotic misuse in the community. Potential self-diagnosis and self-

423   management of upper respiratory infections by the Australian community through use of

424   antibiotic repeat prescriptions is undesirable. [39]

425

426 **Conclusion**

427 In general, pharmacists indicated a high level of appropriateness of antibiotic selection when

428 faced with a range of scenarios as vignettes. More complicated infections tended to be referred to

429 the doctor. The findings of this study warrant consideration by professional bodies regarding

430 expanding the role of pharmacists in the area of limited antibiotic prescribing for limited

431 infections, as one of the strategies to addressing antibiotic misuse in the community and reducing

432 unnecessary inconvenience and cost to the community. This would require the development of

433 prescribing protocols that ensured appropriate prescribing.

434

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437

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Demographic profile of the survey respondents(n = 90), and their association with support for rescheduling of oral antibiotics.

P-values were obtained from the Chi-square test unless otherwise specified.
1   **Table 1:** Demographic profile of the survey respondents (n = 90), and their association with
2   support for rescheduling of oral antibiotics. P-values were obtained from the Chi-square test unless
3   otherwise specified.

Variable n (%)	Number (%)	Number (%) supporting rescheduling	p-value
Gender (n = 90)			0.8504
Female	44 (48.9)	24 (54.6)	
Male	46 (51.1)	26 (56.5)	
Age group (n = 89)			0.9166
21-30	31 (34.8)	17 (54.8)	
31-40	32 (36.0)	19 (59.4)	
41-50	10 (11.2)	5 (50.0)	
51 or more	16 (18.0)	8 (50.0)	
Years registered as pharmacist (n = 88)			0.5045
1 to 5	32 (36.4)	17 (53.1)	
6 to 20	35 (39.8)	22 (62.9)	
21 or more	21 (23.9)	10 (47.6)	
Years worked in a pharmacy (n = 90)			0.9149
1 to 5	25 (27.8)	13 (52.0)	
6 to 20	44 (48.9)	25 (56.8)	
21 or more	21 (23.3)	12 (57.1)	
Position held in pharmacy[*] (n = 93)			
Proprietor	31 (34.4)	18 (58.1)	0.7284
Manager	28 (31.1)	16 (57.1)	0.8386
Pharmacist in charge	23 (25.6)	13 (56.5)	0.9139
Employed pharmacist	6 (6.7)	3 (50.0)	1.0^
Consultant pharmacist	3 (3.3)	2 (66.7)	1.0^
Other position	2 (2.2)	0	0.1948
Pharmacy setting[§] (n = 90)			
Group of shops	24 (26.7)	14 (58.3)	0.7491
City	2 (2.2)	2 (100)	0.5006^
Neighbourhood	23 (25.6)	11 (47.8)	0.3872
Stand-alone	4 (4.4)	2 (50.0)	1.0^
Next to doctor's surgery	14 (15.6)	9 (64.3)	0.4744
Regional shopping centre	12 (13.3)	7 (58.3)	0.8352
Medical centre	10 (11.1)	4 (40.0)	0.3299
Other setting	1 (1.1)	1 (100)	1.0^
Counselling room available	80 (88.9)	45 (56.3)	0.7461^
Forward Dispensing area	38 (42.2)	24 (63.2)	0.2147
Operation size (turn-over)[&] (n = 89)			0.5137
Small (<$1M)	26 (29.2)	13 (50.0)	
Medium ($1M-$2M)	38 (42.7)	24 (63.2)	
Large ($2M+)	25 (28.1)	13 (52.0)	

Pharmacy location (n = 90)			0.9139
Metropolitan	67 (74.4)	37 (55.2)	
Rural	23 (25.6)	13 (56.5)	

4 * There were2 respondents who classified themselves as consultant and proprietor pharmacists, and 1 as consultant
5 and pharmacist in charge
6 & 1 missing response
7 ^ Fisher's Exact Test
8 § Respondents may select 1 or more settings for their pharmacy

Respondents' characteristics associated with their decision to refer a patient to their general practitioner (GP) initially (n =630; results from the Generalised Estimating Equation model).

1 **Table 2:** Respondents' characteristics associated with their decision to refer a patient to their
2 general practitioner (GP) initially (*n*=630; results from the Generalised Estimating Equation
3 model).

Variable	Number (%) referring to general practitioner	Adjusted Odds Ratio	95% CI	p-value
Case type				
Otitis media	13/90 (14.4)	0.13	0.06 - 0.27	<.0001
UTI in pregnancy	37/90 (41.1)	0.64	0.35 - 1.14	0.1279
CAP	32/90 (35.6)	0.49	0.27 - 0.88	0.0168
Tonsillitis	10/90 (11.1)	0.1	0.05 - 0.20	<.0001
Chlamydial urethritis	45/90 (50.0)	0.95	0.57 - 1.58	0.8479
Mid early cellulitis	21/90 (23.3)	0.25	0.13 - 0.47	<.0001
Acute pyelonephritis	46/90 (51.1)	1 (reference)		
Gender				
Female	96/308 (31.2)	0.53	0.32 - 0.91	0.0198
Male	108/322 (33.5)	1 (reference)		
Age group				
51 or more	23/112 (20.5)	0.38	0.18 - 0.84	0.0165
Up to 50	181/518 (34.9)	1 (reference)		
Setting of pharmacy				
Medical centre	34/70 (48.6)	2.29	1.19 - 4.43	0.0137
Other	170/560 (30.4)	1 (reference)		
Size of pharmacy (turnover)				
Small (<$1M)	71/182 (39.0)	2.38	1.21 - 4.69	0.0122
Medium ($1M - $2M)	88/266 (33.1)	1.83	0.92 - 3.63	0.0837
Large (>$2M)	41/175 (23.4)	1 (reference)		
Patients*				
Up to 3 per week	33/63 (52.4)	2.86	1.18 - 6.95	0.0205
4 or more per week	171/567 (30.2)	1 (reference)		
Rescheduling				
Neutral/Disagree	113/280 (40.4)	1.97	1.16 - 3.33	0.0116
Agree	91/350 (26.0)	1 (reference)		

5 *The estimated number of patients per week at pharmacy who would better be treated with oral antibiotics. Numbers
6 are the number *n* of respondents and the percentage in parentheses

Variables associated with appropriateness of therapy selected (*n* =426; results from the Generalised Estimating Equation model).

1 **Table 3:** Variables associated with appropriateness of therapy selected (*n*=426; results from the
2 Generalised Estimating Equation model).

Variable	Number correct (%)	Odds Ratio	95% CI	p-value
Case type				
Otitis media	59/77 (76.6)	0.17	0.05 - 0.60	0.006
UTI in pregnancy	8/53 (15.1)	0.01	0.00 - 0.04	<.0001
CAP	46/58 (79.3)	0.21	0.05 - 0.85	0.0283
Tonsillitis	74/80 (92.5)	0.62	0.15 - 2.58	0.5146
Chlamydial urethritis	39/45 (86.7)	0.37	0.10 - 1.36	0.1337
Mid early cellulitis	66/69 (95.7)	1.16	0.23 - 5.83	0.8528
Acute pyelonephritis	42/44 (95.5)	1 (reference)		
Age group				
51 or more	63/89 (70.8)	0.44	0.22 - 0.88	0.02
Up to 50	266/337 (78.9)	1 (reference)		
Work position				
Consultant pharmacist	9/13 (69.2)	0.32	0.14 - 0.73	0.0068
Other	320/413 (77.5)	1 (reference)		

Figure 1

Respondents' level of support for statements of views on down scheduling of oral antibiotics (*n* =90)
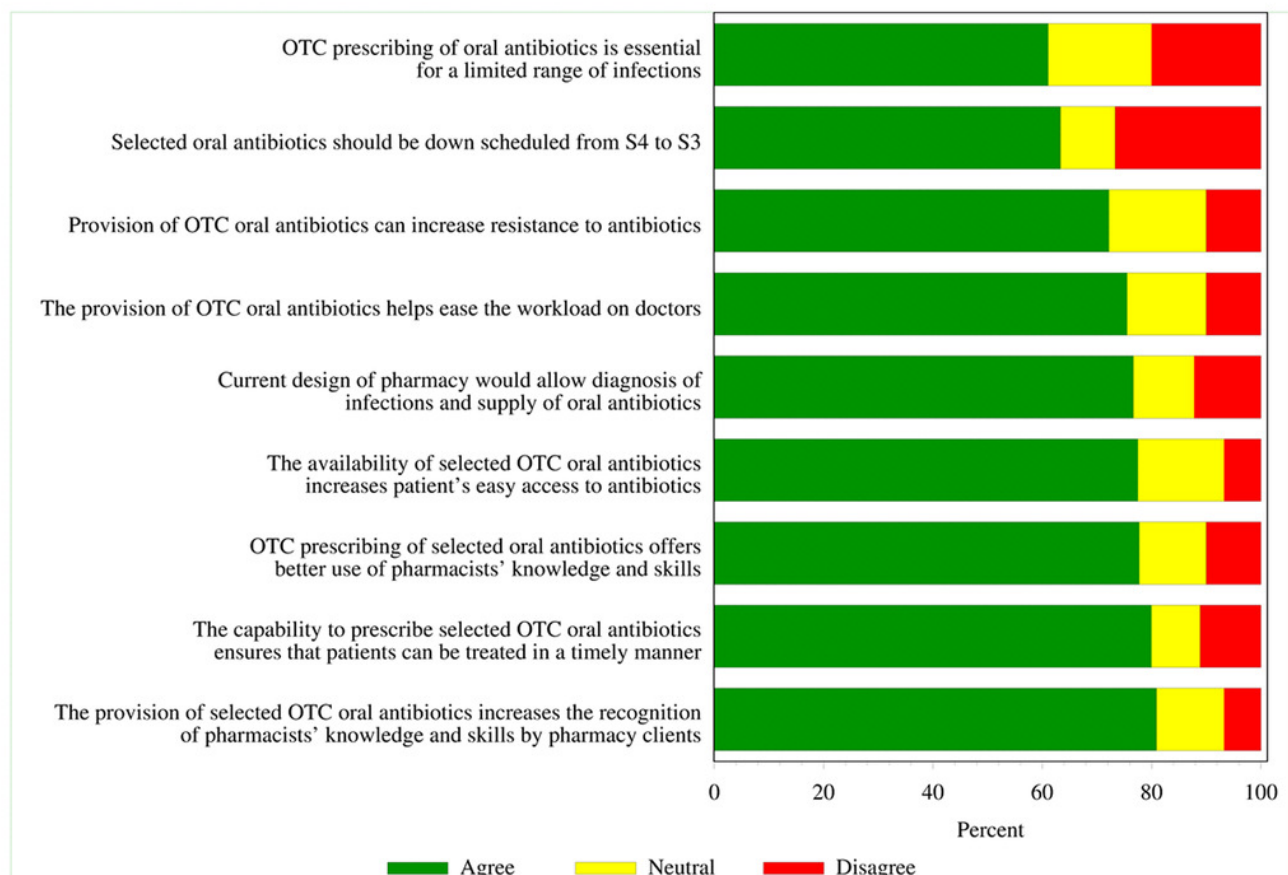
Figure 2

Respondents' level of support for 'down scheduling' of specific oral antibiotics (*n* =90)
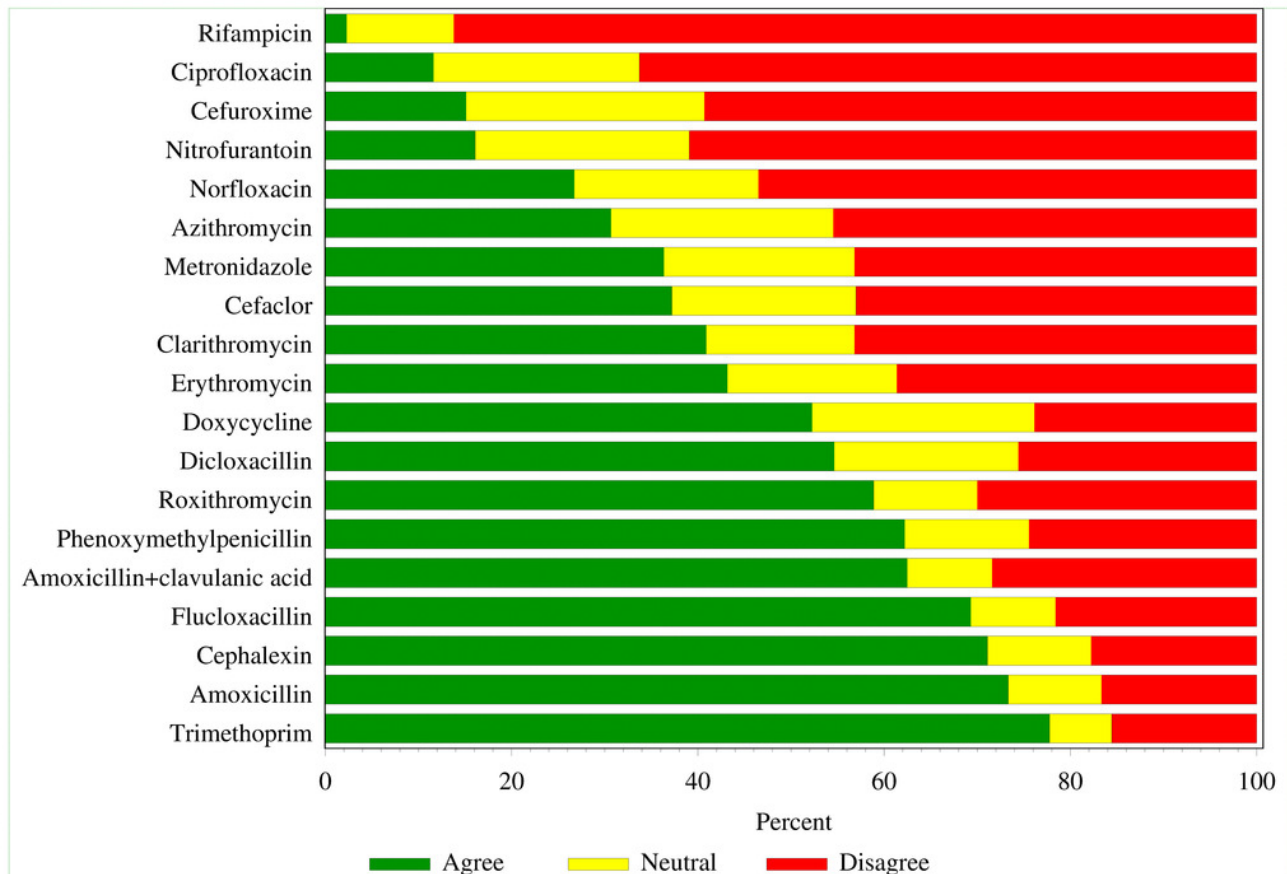
Figure 3

Summary of respondents' choice to refer a patient to a general practitioner (GP) initially rather than treat with an oral antibiotic and the appropriateness of antibiotic selected (*n* =426)
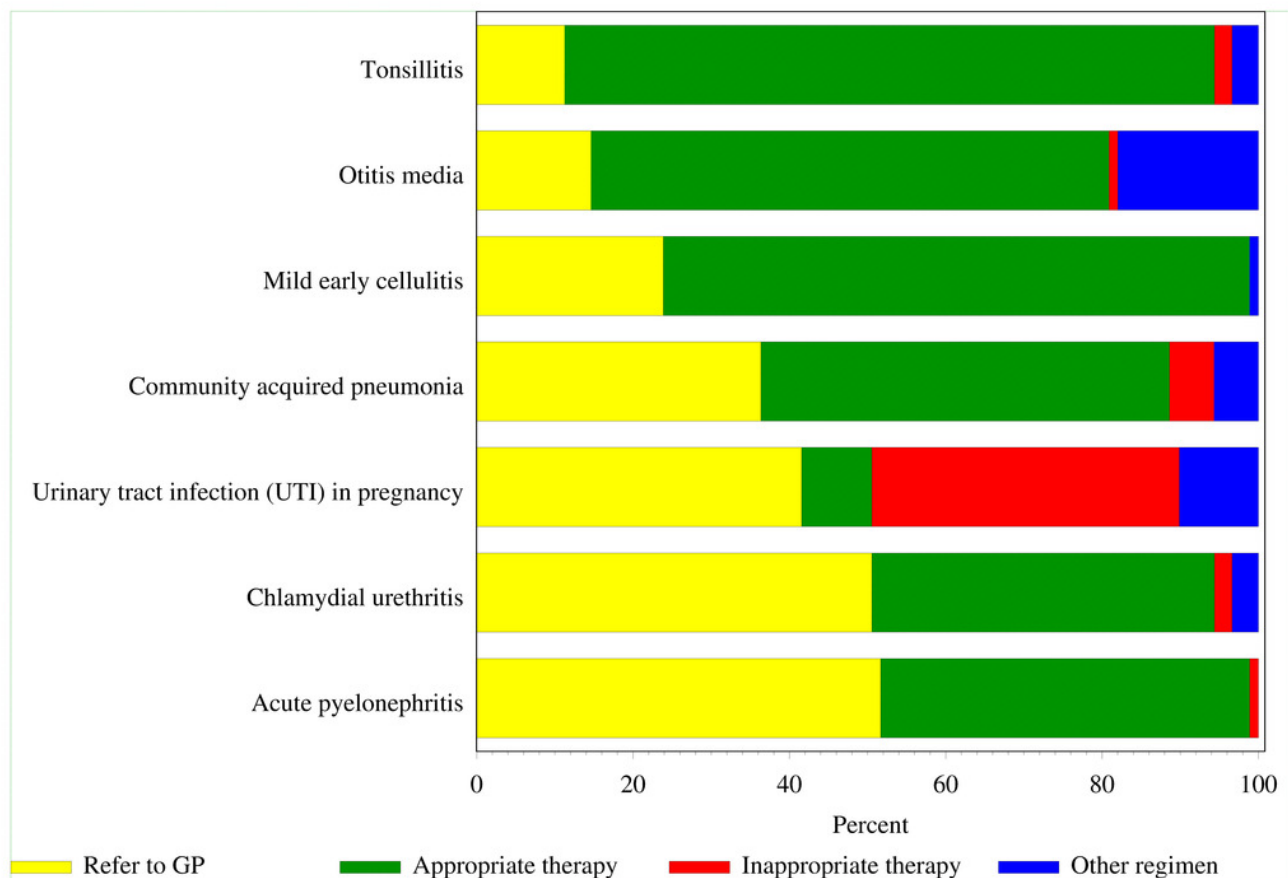
Figure 4

Respondents' level of support for therapy following 3 days (or 24 hours for community acquired pneumonia) of no improvement on initial therapy (*n* =426).

(Note: * 'Other' includes both drug and non-drug therapies).