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Journal of Medicines Optimisation

Developing a patient-centred approach to get best outcomes and value from medicines

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In this issue:

AIM OF THE JoMO

Medicines optimisation is a person-centred approach to safe and effective medicines use to ensure that people obtain the best possible outcomes from their medicines. The aim of the JoMO is to contribute to that process and play an influential and key part in shaping better patient care and the role that medicines can play. The JoMO provides a vehicle to enable healthcare professionals to stimulate ideas in colleagues and/or disseminate good practice that others can adapt or develop to suit their local circumstances.

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The JoMO is made available on a controlled circulation basis to healthcare professionals (e.g. pharmacists, doctors, nurses, etc) and industry colleagues who work with them.

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The JOMO has a network of persons available to provide advice and undertake peer review of articles. Material that appears in the 'Practice Research' and 'Insight' sections will have been subject to peer review.

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Guidance for Authors is available at http://www.jmedopt.com.

All material should be sent electronically to the Editor-in-Chief (alex.bower@pharman.co.uk).

Editorial

Developments in Practice

Community pharmacists and antimicrobial stewardship – what is their role?

What, indeed is their role? The increasing development of antimicrobial resistance is a major concern. Antimicrobials are widely used in primary care so you might think that community pharmacists would have a key role in ensuring appropriate use – but do they? What is the situation in practice? A survey reported in this edition suggests that, whilst there is an encouraging level of input, the amount of information provided is not always as good as it could be. Given that about a third of community pharmacists had not heard of the term 'antimicrobial stewardship'(AMS), there may be a disconnect between the good work that community pharmacists are doing generally and the wider picture. The barriers identified to becoming more involved with the AMS agenda also suggest some disconnect at a clinical level with prescribers and patients. Community pharmacists, or some at least, perhaps need to be reminded that they are key clinical practitioners in their own right and should feel empowered to develop their relationships with the wider clinical team.

Diabetes and Kidney Disease: The Challenging Duo - review article

This comprehensive and well referenced review article discusses diabetes management issues and examines the pharmacological treatment options in patients with diabetic kidney disease, with a focus on glycaemic targets, risks and benefits of the spectrum of oral and injectable hypoglycaemic agents. The advantages and disadvantages of treatment options are described. The review article will hopefully provide some useful background to those involved in the management of patients with diabetic kidney disease.

Patient Perspective

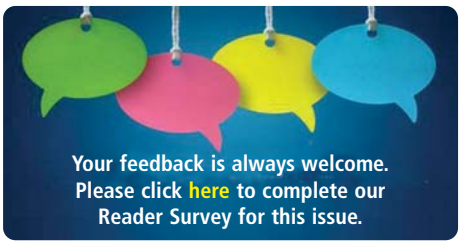
Health professionals may not have talked in as much detail as they would like with patients about their specific condition and what it is like for them living with it on a daily basis. The aim Patient Perspective section aims to rectify that to some extent and assist healthcare professionals in becoming more effective with their interactions and communications with patients. Once you delve behind the immediate medical situation, you may be surprised at the impact that it has on a patient's life from social and other perspectives. In this edition we report on what it is like to have coeliac disease and to feel that your condition is not being taken as seriously as it should. Patients can feel unsupported, isolated and lacking information about their condition. Referral for additional support may be appropriate and patients may, if they have not already done so, find it helpful to contact Coeliac UK (www.coeliac.org.uk) .

TMO (Therapeutic Medicines Optimisation)

Rugby enthusiasts will recognise the term TMO as 'Televsion Match Official' but I am using it here as an acronym for 'Therapeutic Medicines Optimisation'. Initiatives published about medicines optimisation generally address the topic in a general way without reference to a specific therapeutic condition. It is suggested, however, that further progress could be made by having a focus of specific therapeutic conditions. Many pharmacists are now specialists in disease areas and will no doubt have an interest in hearing about initiatives that improve the optimisation of medicine sin their area of expertise. There will no doubt be cross-cutting themes but optimising medicines in, say, diabetes, will no doubt aspects that are specific to that condition and which are, again for example different to respiratory disease.

Readership Feedback

If the JoMO is to continue to publish material that you would find interesting and helpful in your practice, it is clearly important that readers feedback their views. There are various ways in which feedback is currently obtained but, with effect from this edition, a short SurveyMonkey questionnaire that will take just a couple of minutes to complete will be available for each edition.



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Contents

Community pharmacists and antimicrobial stewardship – what is their role?

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Abstract

Title
Community pharmacists and antimicrobial stewardship – what is their role?

Author list
Wilcock M, Wisner K, Lee F.

Introduction
Increasing antimicrobial resistance is one of the pressing concerns globally. As there is widespread use of antimicrobials in the primary care setting, community pharmacists have an important role in ensuring appropriate use of antibiotics. The objective of this study was to assess the views of community pharmacists in one Clinical Commissioning Group towards antimicrobial stewardship.

Method
A survey of a convenience sample of community pharmacists was undertaken using a questionnaire developed following a review of the literature.

Results
Fifty-seven of 62 community pharmacists completed the survey. At the point of dispensing, only 18% of respondents claimed to undertake routine questioning of the patient about the indication for the antibiotic. Nearly two-thirds of pharmacists would wish to check routinely the antibiotic prescribed against local guidelines, time allowing. Advice on completing the antibiotic course was claimed to be always given by 88% of respondents, though only 19% claimed to always advise about avoiding the sharing of antibiotics with others.

Discussion
In this study, we found approximately a third of pharmacists had not heard of the term antimicrobial stewardship. Provision of advice to patients about their antibiotic treatment was not universally undertaken. The majority of pharmacists would wish to monitor antibiotic use as they clinically screen prescriptions as part of their everyday practice, though various barriers (e.g. patient, relationship with the prescriber) were identified.

Conclusions
Community pharmacists and their staff are in a position to support antimicrobial stewardship activities, though improvements are needed in some basic functions such as advice giving at the point of dispensing. Their willingness to challenge inappropriate antibiotic prescribing is an opportunity to be explored and supported.

Keywords: antimicrobials, community pharmacist, communication, patient education.

Introduction

Antimicrobial medicines play a major role in controlling infectious diseases. However, their widespread use – often overuse and misuse – is causing growing resistance to their efficacy. The implications of antimicrobial resistance are a major threat to future healthcare, hence one of the key challenges – globally, nationally and locally - is to ensure the best use of antibiotics. The term 'antimicrobial stewardship' (AMS) is collectively used for a number of quality improvement activities focused on increasing and sustaining the appropriate use of antimicrobials for the treatment and/or prevention of infectious diseases. It is in primary care that the greatest proportion of antibiotics is prescribed, therefore AMS programmes need to be extended to and integrated with primary care. Though all healthcare workers, as well as the public and patients, have a role in tackling antimicrobial resistance, various organisations

have recognised the importance of utilising the skills and training of the community pharmacist to contribute to the reduction of antimicrobial resistance.[1,2,3]

The WHO Regional Office for Europe has undertaken a study investigating the role of pharmacists in respect to encouraging prudent use of antibiotics and prevention of antibiotic resistance emergence and found that pharmacists are among the best positioned health professional group to tackle antibiotic resistance.[4] It is argued that the pharmacist, who has the last contact with the patient before he or she receives an antibiotic medicine, is in a position to act as gatekeeper. Various recommendations have been made for action that pharmacy teams can undertake.[5] For instance, it is suggested that pharmacists have an important role to play in monitoring antibiotic use as they clinically screen drugs as part of their everyday practice. In addition, people have considerable trust in advice about antibiotic treatment from GPs, nurses and pharmacists.[6] However, there remains limited research in the area of community pharmacists and their role in the optimisation of antibiotic prescribing.

We set out to ascertain the views of community pharmacists to their actual and potential roles in AMS in one clinical commissioning group (NHS Kernow CCG) which has 102 community pharmacies. The CCG Prescribing Team has a pharmacist dedicated to promoting AMS activities across primary care and, in the main, messages and activities directed at general practice are also shared with community pharmacy.[7] In addition, specific resources (e.g. patient information leaflets and promotion of the antibiotic guardian resource and pledge campaign for Antibiotic Awareness Day), have been distributed to community pharmacies.

Method

A review of the literature was undertaken to develop the survey questions, which were piloted with two pharmacists. Minor amendments were made. The questionnaire (available upon request from the authors) had a brief introduction describing the problem of antimicrobial resistance and consisted of closed questions with predetermined answers (some of which were multiple choices) though two questions had the option for free text answers. The questionnaire was handed out at an evening meeting, organised by the CCG and Local Pharmaceutical Committee, in March 2017. If community pharmacists wished to participate in some of the CCG-commissioned pharmacy services they had to attend this training meeting or, alternatively, complete online training. Pharmacists were asked to complete the questionnaire upon arrival and prior to the commencement of the meeting. The small number of other pharmacy team members who were not pharmacists were not expected to complete the questionnaire.

Results

Fifty-seven (92%) of the 62 pharmacists attending the event completed the survey. Responses were received from a mix of manager/sole pharmacists (36, [63%]), locum (9, [16%]), superintendent (5, [9%]), additional pharmacist (4, [7%]), and other (3, [5%]). No other demographic information of the participants was collected.

Thirty-five (61%) respondents had heard of the term AMS and 22 (39%) had not. Of the 35 who had heard of this term, 24 (69%) felt confident in their understanding of its meaning. Table 1 shows that only 21 pharmacists (37%) claim that in their

Hardly ever other than ‘special’ circumstances	31 (54%)
More often than not	11 (19%)
I try to do this routinely	10 (18%)
Never	5 (9%)

Table 1: Frequency with which the pharmacy team asked the patient what condition/infection was being treated when dispensing an antibiotic prescription

Patients may not know the diagnostic name of their infection	41 (72%)
Patients may not wish to tell the pharmacist of their infection	40 (70%)
My relationship with local prescribers would be harmed by this checking	14 (25%)
I’m not confident enough about antibiotics, even with access to the guidelines, to challenge the prescriber	11 (19%)
Typically, in my experience, it is not the patient who presents with the antibiotic prescription	10 (18%)
I and my staff have no time to do this asking and checking in the pharmacy	8 (14%)

Table 2: Potential barriers to the role of clinically checking an antibiotic prescription against local guidance (respondents could tick all that apply)

pharmacy there is a standard approach to questioning the patient as to the indication for the dispensed antibiotic.

When asked if they thought they had a role in challenging the prescriber, assuming they knew the infection being treated and had checked the antibiotic prescribed against local guidelines, 35 (61%) responded "Yes I would wish to do this routinely, time allowing", 20 (35%) responded "I might be able to do this but not routinely", and 2 (4%) responded "I would not wish to be involved in this role." Table 2 illustrates the extent to which pharmacists perceive barriers to assuming the role of clinically checking an antibiotic prescription against local guidance.

When asked to reflect on practice in their pharmacy and how often patients are asked about antibiotic adverse effects at the point of dispensing, 22 (39%) answered more often than not, 19 (33%) try to do this routinely, and 16 (28%) hardly ever other than in 'special' circumstances. No one answered that they never do this. In response to the question asking if they or their staff verbally advise the patient or carer to always complete the course when handing over dispensed antibiotics, 50 (88%) indicated yes and 7 (12%) indicated this occurs sometimes. Similarly, when asked if they or their staff verbally advise the patient or carer not to share antibiotics with others when handing over dispensed antibiotics, 11 (19%) answered yes, 36 (63%) answered no, and 10 (18%) sometimes.

There were 34 free text responses to the question asking what they thought the community pharmacist could do to help tackle antimicrobial resistance. The main themes described were patient education, information and awareness on appropriate antibiotic use and the likely duration of any infection; offering alternative options for managing mild infections; collaboration with local GPs to improve antibiotic use; clinically checking antibiotic prescriptions from dentists; supporting adherence with the antibiotic regimen e.g. with the new medicines service.

Discussion

In spite of the prominence given to AMS,[5,8] we found that a third of community pharmacists reported that they had not heard of the term, and of those that had heard this term just under a third lacked confidence in understanding its meaning. We also identified similar gaps in the content of the interaction between the patient and the pharmacy team member as reported in a recent survey of 50 pharmacists from northern England.[9] In our survey, 37% (21) answered that staff do explain about the avoidance of sharing antibiotics with friends and relatives at least some of the time, whereas Clifford and colleagues noted that 52% (26) pharmacists communicated about this.[9] Other comparative results are that 88% (50) of our respondents explained about completing the course versus 62% (31) of pharmacists in northern England. As regards asking the patient what the antibiotic is for, our responses range from 9% (5) answering never to 54% (31) answering hardly ever other than in special circumstances, yet in the northern England survey 30% (15) pharmacists never ask the patient this question.

Clinical screening of prescriptions

In the northern England survey, pharmacists showed poor results when asked whether they checked prescriptions against their local area antimicrobial prescribing guidelines, with 76% (38) not doing so. We did not specifically ask whether this actual checking occurs in Cornish pharmacies, though we did ask if this was a role for the pharmacy staff in challenging the prescriber if they knew the infection being treated. Only 4% (2) responded that they would not wish to undertake this role. However, as only 37% (21) of our respondents claimed to ask the patient what infection is being treated, this suggests that pharmacy teams cannot be clinically checking prescriptions as completely as they should be. Our respondents identified a range of barriers to this act of checking against guidance such as patients not knowing their infection or not wanting to divulge it to the pharmacy team. Interestingly, in the northern England survey 15 (30%) never ask what an antibiotic is for and qualitative data showed that pharmacists thought this question too sensitive to ask a patient. It has been suggested that adding the indication for a medicine onto a prescription may be of value; however this notion appears not to have been formally evaluated and, in relation to antibiotic prescriptions, though it would assist the pharmacist in checking against local guidance patients may not wish the reason for the antibiotic to be widely known.

A qualitative study from Australia with 24 community pharmacists exploring their role in the optimisation of antibiotic prescribing and utilisation identified four main themes.[10] These were patient perceptions and behaviours, prescribing behaviours, pharmacists' roles and responsibilities, and health care system interventions in relation to antibiotic utilisation. Under the theme of roles and responsibilities, pharmacists emphasised the need for greater patient education and counselling by pharmacists to ensure the optimal use of antibiotics. Indeed, various studies have shown confusion among consumers about the efficacy of antibiotics in the treatment of colds and flu and a lack of knowledge despite education campaigns. One such study concludes that there is a need for pharmacists (and other health care professionals) to elicit beliefs and understanding about antibiotics and to tailor advice appropriately according to the health literacy of each patient.[11] Though the theme of patient education emerged in the free text responses in our Cornish survey, we do not know how skilled the pharmacists are at identifying and responding to health literacy issues.[12]

In the Australian study[10] participants did agree that it is the pharmacist's responsibility to confirm that antibiotic prescribing follows current therapeutic guidelines as well as checking for any significant interactions or allergies. However, they felt that the extent to which they could influence the physician's prescribing behaviour was dependent on their relationship with the physician. Again, an American study, conducted in the late 1990s, was undertaken to examine influences on community pharmacists' communication with consumers about antibiotics and antibiotic resistance.[13] Whereas most pharmacists agreed that their role in educating patients is important, they also noted several barriers prevent them from engaging in campaigns, such as time constraints, lack of educational materials, and fear of harming relations with physicians. This theme of harming the relationship with the prescriber by checking the antibiotic prescribed against local guidance was noted by one-quarter of our respondents. Effective communication between pharmacist and physician has to be a core feature of antimicrobial stewardship.

Limitations

Limitations of this small Cornish study include the relatively small sample size undertaken in just one CCG. The number of pharmacists working across our 102 pharmacies is uncertain but we estimate that the 57 responses represents about a quarter of the regular pharmacist workforce and from a third of the pharmacies. Hence the findings of this study may not be as applicable to community pharmacists in other settings. We also recognise the reliance of the survey on self-reporting with the associated potential for social desirability bias where respondents may give expected answers. Attempts to minimise this tendency were made by emphasising that the responses would be processed anonymously. In addition, there are limitations associated with delivering a survey that was brief and consisted of closed-ended questions which limit the answers of the respondents to those options provided on the questionnaire, albeit these responses were based on the literature review.

We did not ask about other possible community pharmacy services related to antimicrobial activities such as vaccination,[14] the provision of TARGET patient information leaflets adapted for use within community pharmacy, or enhanced services such as supply of antibiotics for urinary tract infection as a minor ailment service, point of care testing within pharmacies, or test and treat service for sore throats.[15]

Conclusion

Community pharmacists and their staff are in a position to support AMS activities, though improvements are needed in some basic functions such as providing information at the point of dispensing on the appropriate use of antibiotics, emphasising the need to finish the course, and not to save antimicrobials for another infection or to share them with others. Their willingness to challenge inappropriate antibiotic prescribing is an opportunity to be explored and supported by the CCG and Local Pharmaceutical Committee, potentially utilising general practice pharmacists as a means of enhancing the adoption of a collaborative approach to AMS between community pharmacy and the surrounding general practices.

Declaration of interests

The authors having nothing to declare.

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It would be helpful to have articles that addressed the medicines optimisation initiative for *specific therapeutic areas.* Sharing such targeted work will hopefully facilitate discussion and the implementation of best practice within specialisms.

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Diabetes and Kidney Disease: The Challenging Duo - review article

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Abstract

Title
Diabetes and Kidney Disease: The Challenging Duo - review article

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Summary
This review article will discuss diabetes management issues and examine the pharmacological treatment options in patients with diabetic kidney disease, with a focus on glycaemic targets, risks and benefits of the spectrum of oral and injectable hypoglycaemic agents.

This article aims to increase awareness of the advantages and disadvantages of the available treatment for diabetes to support the safe prescribing, monitoring and optimisation of therapy in this patient population.

Keywords: diabetic kidney disease, hypoglycaemic agents, glycaemic targets, insulin.

Background

Managing diabetes in patients with kidney disease is challenging because renal disease can complicate glycaemic control.

There are an estimated 4.5 million people living with diabetes in the UK.[1] Since 1996, the number of people diagnosed with diabetes in the UK has more than doubled.[1] It has been well established that diabetes is one of the most common causes of kidney disease.[2] Although the development of diabetic nephropathy is slow and usually takes at least twenty years to develop, about 3 in 4 people with diabetes will develop some stage of kidney disease during their lifetime, with nearly 1 in 5 developing overt kidney disease. However, end-stage renal disease, for which renal replacement therapy is required, appears to be decreasing in people with both types of diabetes.[1] This is most likely related to improved management, tighter glycaemic control and earlier detection in type 2 diabetes.

Glycaemic targets

The National Institute for Health and Care Excellence (NICE) recommends that clinicians should work with people with type 2 diabetes to achieve an HbA1c target of <53mmol/mol.[3]

Guideline	HbA1c target
NICE[3]	<53mmol/mol (7.0%)
ADA/EASD[4]	Around 53mmol/mol (7.0%)
International Diabetes Federation[5]	
Functionally independent	53 -59 mmol/mol (7.0-7.5%)
Functionally dependent	53-64 mmol/mol (7.0-8.0%)
Frail elderly or with dementia	<70 mmol/mol (8.5%)

Table 1: National and international recommendations on HbA1c targets for type 2 diabetes

Drug class	Advantages/benefits	Disadvantages/risks	Recommendations
Biguanide (metformin)	• Extensive experience • No hypoglycaemia • Weight neutral • Benefits in reduction in macrovascular complications	• Renally-cleared, accumulation in renal impairment, increased risk of lactic acidosis • GI side effects • Frequent dosing schedule	• eGFR 30-45: starting treatment not recommended, review existing treatment • eGFR <30: contraindicated • Withhold in acute kidney injury, sepsis, acute cardiac or respiratory failure → increased risk of lactic acidosis
Sulphonylureas	• Rapid correction of hyperglycaemia	• Hypoglycaemia is common • Weight gain • Accumulation in renal impairment for those cleared by the renal route	• If a sulphonylurea is required, avoid long-acting sulphonylurea in renal impairment
Postprandial regulators (meglitinides)	• Short-acting, flexible dosing schedule • Lower risk of hypoglycaemia compared to sulphonylurea • Repaglinide suitable in moderate renal impairment	• Frequent dosing schedule	• Nateglinide not recommended in moderate renal impairment
Pioglitazone	• No hypoglycaemia • Once daily dosing • No dose adjustment in moderate to severe renal impairment	• Weight gain • New onset/worsening of heart failure (due to water retention) • Increased bone fractures	• Not recommended in those with heart failure, osteoporosis
DPP4 inhibitors	• No hypoglycaemia • Weight neutral • Once daily dosing	• GI side effects • Pancreatitis	• Linagliptin – no dose adjustment at any stage of renal impairment • All others require dose adjustment according to renal function
SGLT2 inhibitors	• No hypoglycaemia • Weight loss • Once daily dosing	• Genitourinary infections • Dehydration/ hypotension • Risk of euglycaemic DKA	• Initiation not recommended in eGFR<60 • Close blood pressure monitoring when used with diuretics, dapagliflozin and canagliflozin not recommended in patients receiving loop diuretics • Patient counselling on recognition of signs and symptoms of dehydration and DKA • Withhold treatment during acute medical illness or in the perioperative period with presence or risk of dehydration

Table 2: Summary of the advantages and disadvantages of oral hypoglycaemic agents

However, it also emphasises the need to consider patient factors and preferences when individualising glycaemic targets, which is supported by the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD) in their position statement for the management of hyperglycaemia in adults with type 2 diabetes.[4]

Treatment targets recommended by national guidelines are illustrated in Table 1. Glycaemic targets for patients with renal impairment follow the recommendations for the general type 2 diabetes population. The Kidney Disease Outcomes Quality Initiative (KDOQI) guidelines for Diabetes and Chronic Kidney Disease[6] endorsed a target HbA1c of around 53mmol/mol for this patient group.

Oral hypoglycaemic agents (OHAs) – which is the best for my patient with kidney disease?

The current spectrum of therapeutic options for managing hyperglycaemia is fascinating. However, for many, it is recommended that they be used with caution in renal impairment. Clinicians need to be mindful of the impact of chronic kidney disease (CKD) on the choice of OHA. Table 2 summarises the risks and benefits of each class of OHA and highlights the associated recommendations to promote safe use of these agents.

Metformin has extensive evidence and is the first agent of choice for patients with type 2 diabetes if tolerated. It can be used as an adjunct to insulin for people with type 1 diabetes to reduce insulin doses.[3,7] Recent updates from the FDA[8] and EMA[9] extended the use of metformin in renal impairment based on evidence confirming the relative safety of metformin in patients with moderate renal impairment. Starting metformin in patients with an eGFR between 30-45 mL/minute/1.73 m^2 is not recommended. For patients already taking metformin, the benefits and risks of continuing treatment should be assessed when eGFR falls below 45 mL/minute/1.73 m^2 and treatment should be discontinued when eGFR is below 30 mL/minute/1.73 m^2. As a result, the product information has been updated, recommending a maximum daily dose of 2,000 mg/day in CKD stage 3a (GFR = 45-59 mL/min) and 1,000 mg/day in CKD stage 3b (GFR = 30-44 mL/min).[10]

Sulphonlyureas are effective in the rapid reduction of plasma glucose level and the alleviation of osmotic symptoms, but hypoglycaemia is a well-recognised side effect.[11,12] The UKPDS[13] showed that the mean annual incidence of patients experiencing at least one hypoglycaemic episode of any intensity over a 10 year period was 11.0% with chlorpropamide, 17.7% with glibenclamide, and 36.5% with insulin. Study data collected from the Clinical Practice Research Datalink (CPRD), which contained medical records for more than 11 million patients from 674 practices in the United Kingdom, found a 2.5-fold increased risk of hypoglycaemia in patients taking sulphonylurea monotherapy compared to patients taking metformin monotherapy.[14] This higher risk of hypoglycaemic events was further increased in patients with an eGFR <30 mL/min/1.73 m^2, with a 4-fold increased risk in patients with impaired renal function taking suphonylurea monotherapy compared to patients with impaired renal function taking metformin monotherapy. The risk of hypoglycaemia was also significantly higher in patients taking a higher sulphonylurea dose (>10 mg glibenclamide or equivalent). Gliclazide, the sulphonylurea of choice in UK practice, showed a similar risk of hypoglycaemia compared with glimepiride, glipizide, and tolbutamide.[14] However, a systematic review examining the risk of hypoglycaemia when sulphonylurea is added onto metformin monotherapy identified gliclazide to be the sulphonylurea of lowest hypoglycaemia risk compared to glipizide, glimepiride, and glibenclamide.[15] It has also been observed that hypoglycaemia rates are higher in people with CKD with or without diabetes compared to those with normal renal function.[16]

Postprandial regulators, namely repaglinide and nateglinide, like sulphonylureas, stimulate insulin release by closing KATP channels on pancreatic β-cell membranes.[4] Although they are not commonly prescribed in UK practice among other OHAs, they have a place in therapy and an advantage in renal impairment. With its rapid onset and short duration of action, it has the advantage of increased dosing flexibility. To avoid hypoglycaemia, if a meal is omitted, the corresponding dose should also be omitted. Nattrass et al[17] demonstrated that treatment with repaglinide provided similar glycaemic control determined by HbA1c compared to treatment with a sulphonylurea, with an absolute risk reduction of 60% for major hypoglycaemia. Metabolism of repaglinide has been shown to be unaffected by mild to moderate renal dysfunction, due to it being extensively metabolised in the liver to inactive metabolites.[17] In contrast, the active metabolite of nateglinide is renally-cleared and nateglinide should not therefore be used in moderate renal impairment (eGFR <60 mL/minute/1.73 m^2). However, its active metabolite is cleared by haemodialysis, hence nateglinide is safe to use in patients undergoing haemodialysis.[18]

Pioglitazone has demonstrated both efficacy and safety in renal impairment for which dose adjustment is not required and rarely causes hypoglycaemia. However, its side effect of water retention can limit its use in patients with heart failure and in CKD, in particular dialysis patients.[19] It also increases the risk of bone fractures, which can also limit its use in those with increased bone loss, such as in renal osteodystrophy.[18]

The dipeptidyl-peptidase-4 (DPP4) inhibitors, inhibit the enzymatic breakdown of glucagon-like-peptide 1 (GLP-1), causing an increase in insulin secretion responsive to food intake.[20] They are all suitable for use with dose adjustment in moderate to severe renal impairment, with the exception of linagliptin, which does not require dose adjustment in any stage of renal impairment due to its excretion via the bile.[21] Lower doses of sitagliptin (25mg daily) can be used in patients on haemodialysis and peritoneal dialysis.[22] Saxagliptin is not recommended in ESRD patients requiring dialysis.[23] Vildagliptin at reduced dose should be used with caution in ESRD and haemodialysis patients due to limited clinical data.[24] Lower doses of alogliptin (6.25mg daily) can be used in dialysis; however, alogliptin has not be studied in patients on peritoneal dialysis.[25]

Sodium glucose transporter 2 (SGLT2) inhibitors are effective in improving glycaemic control and promote weight loss by reducing glucose reabsorption in the proximal renal tubules, leading to glucosuria and calorie loss.[26] They have been shown to achieve a moderate HbA1c reduction of approximately

0.66–1.03%,[27,28,29] whilst associated with a low hypoglycaemia risk and moderate weight loss of 2–3 kg.[30-33] Side effects are mainly attributed to the associated glucosuria, which include genitourinary infections, dehydration and hypotension. Efficacy is dependent on good renal function, hence they are not recommended for treatment initiation in renal impairment with eGFR <60 mL/minute/1.73 m.[2,27,28,29] Treatment with canagliflozin and empagliflozin are licensed to be used down to eGFR 45 mL/minute/1.73 m[2,28,29] but with a compromise in significant decrease in efficacy. A 24-week study showed a non-significant reduction of HbA1c of 0.41% and 0.44% with dapagliflozin 5mg and 10mg vs 0.32% with placebo in moderate impairment.[34] A 26-week trial in patients with GFR 30-50 ml/minute demonstrated an HbA1c reduction of 0.33% and 0.44% with canagliflozin 100mg and 300mg vs placebo.[35] A study using empagliflozin 25mg in 374 patients with GFR 30-60 ml/minute found an HbA1c improvement of 0.37% compared to placebo.[36]

In response to recent reports of severe and life-threatening euglycaemic diabetic ketoacidosis (euDKA) in patients treated with a SGLT2 inhibitor, an EMA[37] safety alert was published with recommendations for high-risk groups such as those with low insulin-producing capacity, a sudden reduction in insulin dose,

GLP-1 agonist	Dosing recommendation in renal impairment (eGFR in mL/min/1.73 m²)	Safety & efficacy	Risks/adverse effects
Exenatide	eGFR >50: 10mcg BD eGFR 30-50: 10mcg BD (with caution) eGFR <30: avoid	Well tolerated in mild to moderate renal impairment[46]	• Case reports of AKI, not appeared to be directly nephrotoxic, possible natriuretic effect causing dehydration[47,48,49]
Exenatide modified-release	eGFR >50: 2mg weekly eGFR <50: avoid		
Liraglutide	eGFR >30: 1.2-1.8mg OD eGFR <30: avoid	Patients with GFR 30-59 with liraglutide 1.8mg vs placebo as add-on at 26 weeks:[50,51] • HbA1c reduction (1.05% vs 0.38%), weight loss, fewer hypoglycaemic events • Tolerated with no change in renal function UK clinical practice audit[52] findings indicate liraglutide 1.2mg is safe and efficacious in mild to moderate renal impairment	Higher GI side effects in those with renal impairment[52]
Lixisenatide	eGFR >50: 20mcg OD eGFR 30-50: 20mcg OD (use with caution) eGFR <30: avoid	Well tolerated in mild and moderate renal impairment[53] No difference in HbA1c, fasting and postprandial glucose in renal impairment vs normal renal function[53,54]	Increased plasma conc. in moderate renal impairment[53] Higher side effects in those with mild renal impairment[53,54]
Dulaglutide	eGFR >30: 0.75mg or 1.5mg weekly eGFR <30: avoid	Pharmacokinetics similar in mild severe renal impairment (and dialysis) compared to normal renal function[55]	
Albiglutide	eGFR >30: 30mg or 50mg weekly eGFR <30: avoid	Increased glycaemic lowering effect in lower eGFR[56]	Higher GI side effects in severe renal imp[airment compared to mild and moderate renal impairment[56]

Table 3: Summary of safety and efficacy of GLP-1 agonists in renal impairment

during the time of increased insulin requirement (e.g. illness or surgery) or conditions that can restrict food and fluid intake. Clinicians should inform patient of the signs and symptoms of DKA and seek medical attention immediately if these symptoms arise, test for raised ketones in patients presenting with symptoms of DKA and stop treatment if DKA is suspected or diagnosed. Treatment with a SGLT2 inhibitor should be interrupted prior to major surgery or during serious medical illness related to volume depletion.[37]

Injectable therapies – GLP-1 agonists

GLP-1 receptor agonists improve HbA1c by stimulating glucose-dependent insulin release, inhibiting glucagon secretion and promote weight loss by suppressing appetite.[20] This class of agents are contraindicated in severe renal impairment (eGFR <30 mL/minute/1.73 m^2),[39-43] with exenatide modified-release contraindicated in eGFR <50 mL/minute/1.73 m^2.[44] Although use with caution is generally recommended with GLP-1 agonists in patients with moderate renal impairment,[45] there is evidence to support the safety of these agents in mild and moderate renal impairment. Table 3 summarises the evidence on the safety and efficacy of GLP-1 agonists in renal impairment.

Effects of CKD on insulin metabolism

It was found that, compared to people without CKD, the rate of hypoglycemic events was twice that for those with CKD. Moreover, hypoglycaemia affects CKD patients with and without diabetes.[16] This can be explained by the fact that CKD alters the pharmacokinetics of all insulin. Endogenous insulin is released from the pancreas into the portal system, with 40-50% undergoing first-pass metabolism in the liver and 30-80% being metabolised by the kidneys.[57] Conversely, exogenous insulin does not undergo first-pass liver metabolism, hence the kidneys are primarily responsible for exogenous insulin metabolism.[57] A study has shown when creatinine clearance reaches below 20 ml/min, renal clearance of insulin is markedly reduced.[58] CKD patients with residual diuresis of less than 500 ml/day showed a reduction in insulin needs by about 29%.[59] As a result, the risk of hypoglycaemia is increased when the insulin dose is not reduced. Other attributing factors to decreasing exogenous insulin requirements in patients with diabetic kidney disease include reduced renal gluconeogenesis and weight loss associated with uraemia-induced anorexia.[60]

CKD further complicates glycaemic control

CKD patients are more susceptible to plasma glucose fluctuations as some mechanisms in CKD can cause hyperglycaemia. Uraemia-associated insulin resistance is a recognised metabolic alteration in CKD, which begins to occur when creatinine clearance is less than 50 ml/min. Insulin sensitivity can reduce by as much as 60% in uraemic patients in predialysis state.[57] Secondary hyperparathyroidism and vitamin D deficiency reduces insulin-secreting capacity of pancreatic β cells, and medical or surgical therapy has been shown to improve glucose tolerance and insulin secretion.[57]

HbA1c may be a misleading measure of glycaemic control in patients with CKD, which is associated with a shortened red cell survival and HbA1c can be falsely low. However, other processes in CKD, such as decreased erythropoietin production, higher levels of carbamylated haemoglobin, and higher glucose exposure during dialysis, can raise the HbA1c.[61] Generally, HbA1c tends to be falsely lowered in chronic renal failure.[61,62]

What do the guidelines say about insulin therapy in CKD patients?

There are no specific national guidelines on insulin management in this patient group with recommendations on glycaemic targets and most appropriate insulin regimens, which places the emphasis on individualisation of therapy. Table 4 shows the general recommendation from the American College of Physicians on insulin dose adjustment for people with CKD.

The management of patients with diabetes and kidney disease is complex and optimising glycaemic control can be difficult due to the effects of concurrent nephropathy, in particular in those undergoing renal replacement therapy.

Glycaemic targets should be individualised and optimal glycaemic control is achievable with careful selection from the wide range of diabetes treatment options. Patients should be closely monitored for medicine-related adverse effects and disease progression.

The prevention and treatment of diabetic kidney disease and related complications requires a multidisciplinary specialist teams approach.

Declaration of interests

The author reports personal fees as Consultancy advisor for Eli Lilly UK, outside the submitted work.

Renal function	Insulin dose adjustment
eGFR >50 ml/min	No dose adjustment is required
eGFR 10–50 ml/min	Reduce dose by 25%
eGFR <10 ml/min	Reduce dose by 50%

Table 4: General principle on insulin dose adjustment in CKD[60,63]

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Patient Perspectives

The process of medicines optimisation places patients at the heart of the process. It seems only right, then, to seek the views of patients about their experiences with medicines, their medical condition in general and their contacts with health professionals. Understanding what it is really like for a patient to live with a particular clinical condition will hopefully assist healthcare professionals to become more effective with their interactions and communications with patients and improve the healthcare services provided.

This has been done by providing patients identified through healthcare contacts with a template of questions to be completed anonymously by the patient on the basis that no individual be named or identifiable from the content. What some people have to cope with and the way they do it will amaze you.

Coeliac Disease

Abstract

Title
Patient Perspective: Coeliac Disease

Summary
A patient's perspective of living with coeliac disease is described. The way contacts with healthcare professionals might have been better are outlined. The medicines taken, elements of service provision found to be most helpful and steps to improve the ongoing management of the condition are outlined. Key messages for healthcare professionals that have arisen from the patient experience are indicated.

Keywords: medical condition, medicines.

About your medical condition

What is the medical condition most important to you that is being presented here?

Coeliac disease

Can you please explain the problems you experience with this medical condition?

When, like me, you have been able to eat what you like for 45 years with no symptoms, bar excessive fatigue, it is a shock when this comes to an end.

I was a silent coeliac. This means that I presented with no other symptoms apart from extreme fatigue and tiredness, which had been going on for the best part of three years. There was no clue that it was coeliac disease causing this, just a barrage of tests with results that weren't making any sense. They tested me for pernicious anaemia and that came back normal! Only then was I tested for coeliac disease, which I now know was positive.

I experienced a sense of loss. One of my favourite pastimes was trying out new food and eating out, but when I was diagnosed the bottom fell out of my world - everything I knew had been taken away.

This all happened one week before my birthday, three weeks before our wedding anniversary and one week before we had a German exchange student, who was the same age as my daughter, had come to stay. The school my daughter attended had told us to serve traditional English food for the exchange student (such as roast dinner or fish and chips). But, as a result of my recent diagnosis, nearly all my quick 'go-tos' had been removed. Normally, for all these type of occasions, going out to eat would have been one of my fun things to do, but this time it just wasn't possible.

In addition to this, I had also planned for everyone come to me for Christmas dinner (ten of them). However, I had no support whatsoever, and socialising became noticeably difficult as people were, and still are, used to me eating everything in sight. It's such

a shame that no-one seems to take much notice of the social effect a diagnosis has. It's caused me all sorts of problems.

Buffets are a nightmare for people with coeliac disease, but sometimes they are the easiest thing for hosts to do. My family also have a habit of going out for lunch on Boxing Day, not having any inkling of the stress that puts me under. The first time this happened I ended up with a not a very good meal, and consequently fell into a foul mood all day just because of the stress as I had no say in where we went. Then everyone was eating the one dish (pasta) that I couldn't have. That was four years ago, but it still grates that the emotional support wasn't there when my whole normal world had been turned upside down. However, through researching about the condition and obtaining information from the support group on the CUK (Coeliac UK) site, things have improved and we can now actually plan a dinner out.

Others will know the look of "oh great, another one on a fad diet" every time you go anywhere and ask for a gluten free menu, of being told "it's only an intolerance" and the infuriating "it's fine if you ring before you arrive", which rips all the spontaneity out of anything. This is never addressed by those who dish out the original diagnosis.

I am very lucky; I'm not allergic to any foods at all, so eating is fun and always has been, but it very nearly ripped the entire heart out of my life because I was never helped or supported to adjust.

Can you please say how the medical condition was first diagnosed?

Via blood test and then an endoscopy into the small intestine.

Can you please say when the medical condition was first diagnosed?

August/September 2012.

If you look back, what would you say have been the main things you would have liked to have been different in terms of contact with health professionals?

Being listened to about feeling extremely tired and telling them that I felt anaemic. All anyone did for nearly three years was test my iron levels for anaemia, which always came back normal. I was contacted by my GP on one of those occasions to say that my B12 was borderline low, was retested and then told it was nothing to worry about.

I saw a really switched on locum, whilst we were waiting for our new GP, who tested me for everything when I mentioned again that my B12 was low and raised the possibility of pernicious anaemia. The results came back as normal for pernicious anaemia but my folic acid and B12 levels were extremely low. This led to the treatment for B12 and folate deficiency anaemia and a blood test for coeliac disease.

The locum listened to what I said, identified that I was eating all the right things but something didn't add up. Hence the test for pernicious anaemia and then coeliac disease.

I think I also would have liked a bit more information about coeliac disease (by this time our GP had arrived) and, to be fair, I was given the website for Coeliac UK (www.coeliac.org.uk) by my GP.

No one helped me to sort my diet except my husband.

I didn't know that bread had to be ordered in by the pharmacy. I also wasn't told that I could finish the food that I had just bought that day to feed my family on a budget. I also wasn't given any sensible advice as to how long sorting my diet out was going to take.

All of these things below I had to ask for which, in reality, should have happened automatically under NICE guidelines:

- referral to dietitian
- referral for DEXA scan
- an annual blood test and review (still having to ask for that now, five years later; it's not automatically done, like it should be).

As a Coeliac I feel sometimes that we are not taken seriously and that our illness isn't valid. Everyone thinks it's easy to be on a gluten free diet - I can assure you, it isn't.

About your medicines

Please list the medicines you taking for your medical condition.

I am on a very strict gluten free diet as there is no other medication for coeliac disease. I do order my food on prescription, especially bread, as it is specially formulated for our diet and takes note of our malabsorption problems.

If I am 'glutened' (i.e. I have eaten something containing gluten), I take the following and, on a couple of occasions, I have still needed the paramedics (but that's the exception, not the rule):

- buscopan (high strength) for the cramps
- paracetamol for the pain and, if that's not enough
- tramadol.

I also take vitamin B supplements every day to try and keep that going and Vitamin D supplements every other day to try and counter the effects of the bad absorption before I was diagnosed. I now have mild osteopaenia in my left hip due to the coeliac disease.

Have you had any particularly bad experiences with regard to your medication? If so, explain and indicate how this could have been avoided in the future.

The pharmacy and the GP surgery have misread and misinterpreted what I have ordered in the way of food, giving me the wrong amount of one food and not enough of the basics (like bread). It took a bit of time but we did eventually iron things out.

Have you any good experiences of your medications? If so, please explain.

The pharmacy and GP surgery now very rarely make mistakes, and due to the fact that I have a good relationship with my local pharmacy they will now ring me if they think something is not quite right. This doesn't happen much now at all, as all of us know what we're doing.

About the services you received

What have you found to be most helpful to you in terms of the services you have received?

The help I have received from the pharmacy and the companies that provide my specialist food - nothing is too much trouble. Other than that, apart from Coeliac UK's website, nothing was really helpful at all.

To what extent have the health professionals you have come in contact with appreciated what it was like from your position as a patient?

They haven't. I had a lot of issues with a sense of loss and frustration, which caused some mental health issues. Nobody thought about the fact that this could be to do with the diagnosis and the impact it had on my social life around fairly major celebrations. The emotional impact is very real, but I don't feel that anyone appreciated it at the time or appreciates that now.

To what extent was the information you were given about your medical condition sufficient for you?

It wasn't. I wasn't helped to shop, to sort out labels or told what I should or shouldn't be looking for in terms of avoiding gluten. I also wasn't briefed on cross contamination or the effects that could have. I was literally given a prescription for bread and pasta but not told it would need to be ordered in and, therefore, that it could take up to four days to obtain. I went back to the surgery to ask for some help and got to see a nurse who told me that I could still eat couscous - which is pasta, so I couldn't but if I had not known that the consequences could have been dire.

Even the people who were supposed to help didn't seem to know what gluten was, never mind what it was in! Very poor.

I needed support in this journey and it wasn't forthcoming.

To what extent did the health professionals you came in contact with communicate effectively with you?

Basically they didn't. My GP was helpful to a point and met every one of my requests, but to this day does not understand how difficult it is for me. As for other professionals, the consultant at the hospital didn't even tell me what was going on; I found that out in a letter, then a phone call from the GP and ultimately an appointment to tell me I had coeliac disease.

When I asked for support the person they sent me to didn't have any idea what was safe and what wasn't, and didn't seem to understand that I needed some help to sort out my diet. The dietitian put a recommendation that I needed an annual blood test in writing. I had to write to the practice manager telling them that it was necessary and why as they originally told me that they wouldn't sanction that!

What have been the best experiences you have had with the services you have received?

Since my letter to the practice manager, I have never been refused any service I have asked for - I always back up my requests with evidence from Coeliac UK, without that support I would not be very confident today.

About other medical conditions

Do you have any other medical conditions that make life problematic for you? If so, please list them and explain the main problems you experience with each one.

Medical condition: main problem experienced
Asthma: Hayfever, causing constant coughing

Depression: I have a history of this. The diagnosis of coeliac disease increased stress levels and had an impact on my mental health, which was not taken seriously.

Menopause: Night sweats, mood swings, stress anxiety (asthma trigger).

About going forward

What would you like to happen at this stage that would make living with your condition easier for you?

Firstly, to stop telling everyone that the supermarkets cater for all our needs. They don't. Nothing on the 'Free From' shelves is fortified with anything, which is daft when you consider that most Coeliacs have issues with absorption of minerals and vitamins and are very often deficient of them.

The price of gluten free food to come down. It is extortionately expensive.

That people acknowledge that coeliac disease is a serious autoimmune condition and is treated as such by professionals in particular.

The general public is under the impression that a Coeliac is not a Coeliac for life and that you can grow out of it; we need to change the perception.

Coeliac UK are doing a fantastic job, but maybe if the professionals took it a little more seriously and listened to their patients concerns we could change some attitudes.

If you could give a brief message to healthcare professionals, what would it be?

Do not dismiss coeliac disease as nothing to worry about. Listen to your patients and, above all, if you are at all suspicious order a blood test. If I had been tested eight years ago, I would not have been wrongly diagnosed with IBS. It affects everyone differently, but don't just ignore the person who keeps coming back saying they feel anaemic; look beyond the basic iron levels.

Support groups for locals with the condition so they can help each other. There may be people in the same boat who could be mentors or who you could ask to go shopping with to help and advise.

Don't just leave us floundering around in the dark with no support, which is what happened to me.

Please add any other comments or observations that would be helpful to health professionals who are responsible for providing services for you.

Any patient would need support with a change in lifestyle. Coeliac UK's website was a good start, but you need to be aware of the social impact. Nearly everything we do culturally in this country revolves around food. The diagnosis makes the patient the outsider and makes them feel very incredibly isolated.

Do not ignore the grieving process, or the problems associated with people not understanding food.

Referral to a dietitian at the earliest possibility would probably have been a lot more helpful to me than it was as I had to wait and request this myself. If that had happened automatically I would have had support when I needed it.

Coeliac disease needs to be taken more seriously than it is, it has a very big impact on the patient as well as everyone around them.

What are the three most important things that health professionals should learn from your experiences?

1) Listen.

2) More emotional support.

3) Referrals straight away.

Declaration of interests

You will have been offered a fee for your contribution to be submitted within a specific timescale. In the spirit of being open and transparent, would you please disclose any other payments, interests or activities that could be perceived as influencing what you have written or state 'none'.

None

KEY LEARNING POINTS FOR HEALTHCARE PROFESSIONALS IDENTIFIED AT THE EDITING/PEER REVIEW STAGES

- Do not underestimate the sense of frustration and isolation that a coeliac patient can experience if they have undiagnosed problems and feel that they are not being listened to. It might be helpful to raise awareness of the Coeliac UK support group.
- The social consequences of a medical condition also need to be taken into account – a referral may be appropriate for advice to improve a patient's quality of life.
- Be prepared to check if a patient feels they have enough information about their condition and, if not, update your knowledge or refer them to someone who can help.

WOULD YOU LIKE TO COMMENT ON CONTENT IN THIS EDITION OF THE JoMO?

READERSHIP QUESTIONNAIRE

A short SurveyMonkey questionnaire that will take just a couple of minutes to complete is available in the Editorial section.

CORRESPONDENCE

Constructive comment to further understanding and debate about a topic is encouraged and welcomed.

Guidance on submitting correspondence appears at the front of the journal.

Please submit your correspondence to the Correspondence Editor: (**correspondence@jmedopt.com**)

LINKEDIN

There is a JoMO LinkedIn Group. It is a closed group but everyone who requests the JoMO will be permitted to join. Readers are encouraged to comment upon and discuss items about medicines optimisation.

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Readers are encouraged to follow Pharmacy Management on @pharman to use our dedicated Twitter hashtag (#jmedopt) to draw attention to and debate topical issues having to do with medicines optimisation.

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