• Barrier to contraceptive use among childbearing age women in rural Indonesia

• Unmet basic needs and family functions gaps in diabetes management practice among Indonesian communities with uncontrolled type 2 diabetes: A qualitative study

• The association between body mass index and the oral Firmicutes and Bacteroidetes profiles of healthy individuals
About MFP

The *Malaysian Family Physician* (MFP) is the official journal of the Academy of Family Physicians of Malaysia (AFPM). It is jointly published by the Family Medicine Specialist Association (FMSA) of Malaysia. The MFP is published three times a year. It also started an Online First section in January 2021, where accepted articles are published online ahead of the issue.

**Goal:** The MFP is an international journal that disseminates quality knowledge and clinical evidence relevant to primary care. The journal acts as the voice of family physicians, researchers and other members of the primary care team on clinical practice issues.

**Scope:** The MFP publishes:

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ii. Education – Case Reports/Clinical Practice Guidelines/Test Your Knowledge. We only encourage case reports that have the following features:
   1. Novel aspects
   2. Important learning points
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The Malaysian Family Physician welcomes articles on all aspects of family medicine in the form of original research papers, review articles, CPG review, case reports, test your knowledge and letters to the editor. The journal also publishes invited debate, commentary, discussion, letters, comment, and editorials on topics relevant to primary care.

Articles are accepted for publication on condition that they are contributed solely to the Malaysian Family Physician. Neither the Editorial Board nor the Publisher accepts responsibility for the views and statements of authors expressed in their contributions. All papers will be subjected to peer review. The Editorial Board further reserves the right to edit and reject papers. Authors are advised to adhere closely to the instructions given below to avoid delays in publication.

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All types of review articles, including narrative review, scoping reviews and systematic reviews are accepted for publication in MFP. A comprehensive review of the literature with a synthesis of practical information for practising doctors is expected. For a systematic review, the PRISMA checklist (https://www.equator-network.org/reporting-guidelines/prisma/) must be followed. For a scoping review, the PRISMA-ScR checklist (https://www.equator-network.org/reporting-guidelines/prisma-scr/) should be followed. The length should not exceed 4000 words with a maximum of 5 tables or figures and 40 references. Please include the following sub-headings in the manuscript:

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EDITORIAL

Malaysian Family Physician (MFP)’s transformation and updates

Ping Yein Lee
Deputy Chief Editor

Lee PY. Malaysian Family Physician (MFP)’s transformation and updates. Malays Fam Physician. 2021;16(3);1. https://doi.org/10.51866/ed0003

Our journal has recently implemented some changes and updates to facilitate manuscript submission and the review process, as well as improve the journal’s content for primary care doctors. The four main enhancements include 1) adding colour to the article pages, 2) establishing the Online First section to expedite the publication of accepted articles, 3) making available a new online submission portal (OJS)\(^1\) and 4) modifying the requirements for and format of case reports.\(^2\)

The new OJS enables authors to monitor the progress and status of their manuscripts in the portal. Authors are also able to communicate with the editors in the portal (in the Add Discussion section). In addition, reviewers can review manuscripts and submit their comments via the online system.\(^1\)

Our journal expects case reports to represent less commonly seen cases and offer educational value for practising primary care doctors. The case must have important learning points and be relevant to primary care practice. The case reports must reflect a patient-centred approach instead of a disease-centred focus. We expect a case presentation to provide a comprehensive account of the presenting features, including the medical, psychosocial and family history.\(^2\) It is advisable to avoid using judgemental or inappropriate terms (for example, “deny”, “failed” and “complaint”).\(^3\) Moreover, we have added two new sections: 1) What is new in this case report compared to the previous literature? and 2) What is the implication to the patients?\(^2\)

With these improvements to the journal, we hope that MFP will continue to serve as an international journal that disseminates quality knowledge and clinical evidence relevant to primary care.

References


Primary palliative care. Caring for patients with life-limiting illness in the community
Sylvia McCarthy
McCarthy S. Primary palliative care. Caring for patients with life-limiting illness in the community. Malay Fam Physician. 2021;16(3);2–5. https://doi.org/10.51866/cm0002

Abstract
The 9th October 2021, was World Palliative Care Day. This year’s theme for world palliative care is “Leave No One Behind – Equity in Access to Palliative Care”. Evidence for the outcomes of early palliative care is growing. In 2014, the World Health Assembly passed a resolution that was co-sponsored by Malaysia. The resolution called for countries to improve access to palliative care as a core component of health systems, with an emphasis on primary health care and community/home-based care. One study conducted in Malaysia in 2019 estimated that by 2030, with the increase in non-communicable diseases, 246,000 patients would require palliative care. For Malaysia to achieve equity in access to palliative care, care for these patients must be integrated into primary care. This article discusses some of the tools available for early identification of patients assessment and management of patients with palliative care needs.

Early palliative care can reduce emergency admissions and support patients to die in their preferred place. Increasing evidence supports the need for early palliative care for patients with organ failure, frailty, and neurodegenerative diseases.

For patients with organ failure, prognostication is inaccurate; with any exacerbation, the outcome may be either sudden death or recovery but with less function than before. The palliative care Bowtie Model (Figure 1) has been proposed to describe the integration of palliative care and disease management across the illness trajectory. This integrated model allows patients and their doctors to plan for their deterioration and end of life while maintaining hope for improvement and good quality of life.

Well-being trajectories show the changes in four dimensions – physical, psychological, social and spiritual – over the course of a life-limiting illness and help health care professionals establish where and when patients need more support (Figure 2).

Keywords:
Palliative care, community, primary care

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Figure 1. The palliative care Bowtie Model.
Figure 2. Four dimensions of wellbeing trajectories.

Community palliative care often refers to the care provided by community palliative care teams who provide specialised services for patients at home. However, these services cannot meet the need for early palliative care. To address this gap, a new definition of Primary palliative care has been proposed; see box 1.

Box 1. Definition of primary palliative care.

Primary palliative care is palliative care practised by primary health care workers, who are the principal providers of integrated health care for people in local communities throughout their life. It includes early identification and triggering of palliative care as part of integrated and holistic chronic disease management, collaborating with specialist palliative care services where they exist, and strengthening underlying professional capabilities in primary care.

This definition recognises that primary care physicians are ideally placed to identify patients living with serious illness who may be suffering from the impact of illness and for whom focusing on quality of life outcomes are now more important than disease outcomes.

Several tools have been developed to help primary physicians identify patients with palliative care needs. One of these is the Supportive and Palliative Care Indicator Tool (SPICT) which has been developed for use in primary care settings to help primary care physicians identify patients under their care who may have palliative care needs. Rather than identifying specific needs, the SPICT identifies those patients who would benefit from further assessment and care planning. The areas where SPICT can help are outlined in box (2) below.

Box 2. Benefits of Using SPICT.

- Offers people opportunities to talk about their health declining and ‘what matters’ to them, including things they hope to do, would like to happen, or wish to avoid.
- Gives priority to maintaining a person’s quality of life, and involving the people who are close to them.
- Ensures that any available disease-modifying treatments of benefit are combined with good symptom control and other aspects of palliative care.
- Reduces the risk of complex treatment and care decisions in a ‘crisis’ by making emergency care plans for acute illness or complications (including for family caregiver changes).
- Encourages people to appoint a proxy decision-maker (Power of Attorney) and/or make ‘advance decisions’ about any treatments they do not want in the future.
- Improves communication, continuity of care, current and future care planning; and multidisciplinary teamwork.
- Includes family members and other carers so they receive the help and support they need.

Wellbeing | Heart Failure
---|---
Distress | acute exacerbations

Trajectories
- Physical
- Social
- Psychological
- Spiritual
Assessment of palliative care needs requires a patient-centred, holistic approach to care. These are core features of family medicine.

What are “palliative care needs”? There is no unified definition, and the needs will be different for each patient. Palliative care needs can be considered in four quadrants: physical, psychological, social and spiritual. For individual patients, these areas cannot be addressed separately; each dimension impacts the others, and holistic care depends on understanding the interplay between them. However, the four quadrants help offer structure to an assessment of palliative care needs. Various tools are available to support palliative assessment. In the physical quadrant, patient-reported outcome measures such as the IPOS and ESAS aid with identifying symptoms and symptom severity. These tools are simple to use and include questions about mood and well-being.

The distress thermometer, which was developed in cancer care, is a useful screening tool for distress and identifying the factors causing the distress.

Box 3. Definition of spirituality in palliative care.

| Spirituality is the aspect of humanity that refers to the way individuals seek and express meaning and purpose and the way they experience their connectedness to the moment, to self, to others, to nature, and to the significant or sacred. |

Following a detailed holistic assessment focusing on the patient’s and family’s concerns, goals of care can be discussed. The model of shared decision-making is useful in this context. Symptom management aimed at achieving the patients’ priorities can be started and disease management optimised.

Success in providing primary palliative care depends not only on primary care physicians but also on access to medication and coordination of care. In the case of patients with life-limiting illnesses, we know there is significant suffering, however we do not know the specific experiences of Malaysian patients in their last year of life. We need more research to inform service development. Patients start their illness journey at home in the community, and in most parts of the world, patients want to be cared for close to home. Can we provide the care they need in the place they want to be?

What about care at the end of life when patients are dying? In Malaysia, we still lack data about patients’ preferences for care and what they would consider a good death. Studies of patients and carers in both Asian and Western cultures have demonstrated some similarities in what is regarded as important at the end of life, and broad agreement exists regarding pain and symptom control, preparation for death, completion, contributing to others, not being a burden to others and maintaining hope. Nonetheless, because culture influences the meaning that people give to illness, suffering and dying, we need research that reflects the realities in our communities.

Using the place of death as a marker for quality of care is a topic of debate. Although most patients would like to be at home at the end of life, they prioritise good symptom control at the end of life. Palliative care home services with skills in pain and symptom management and access to medication as well as provision of emergency cover can support caring for patients at home. However, at present, these services...
are only available in urban settings, leaving most patients with no option but to seek care in hospital or suffer in pain.

There are many challenges ahead if patients are to have their palliative care needs addressed in the community, but family medicine physicians and general practitioners are ideally placed to take the first step by identifying patients early, and providing proactive, anticipatory care. Those with positions of influence in policy making can advocate to improve access to services and medication and relieve some of the burden associated with having to access hospital care.

References


The short child: Importance of early detection and timely referral

Meenal Mavinkurve, Azriyanti Bt Anuar Zaini, Muhammad Yazid Jalaludin


Abstract

Stunting is a common phenomenon in Malaysian children. Optimising outcomes for children with growth disorders rests on early recognition and prompt referral. In this context, a framework for the clinical approach can help to guide appropriate growth assessment and referral. This review article aims to provide family medicine specialists with a framework whilst raising awareness about the shortcomings of the existing growth monitoring system in Malaysia. It also invites readers to consider additional measures that could further optimise this system.

Childhood stunting in Malaysia

One of the many child health goals from the World Health Organisation (WHO) 2025, which Malaysia is aiming to achieve, is a 40% reduction in childhood stunting. In 2019, statistics from the National Health Morbidity Survey (NHMS) reported that 21.8% of Malaysian children under the age of 4 years are stunted and that stunting in 2017 (16.6%) and 2016 (20.7%) were not much different. Within Malaysia, there is a disparity in the rates of stunting, with higher rates in Kelantan (34%), Terengganu (26.1%) and Pahang (25.7%) and the lowest rates in Kuala Lumpur (10.5%).

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Stunting, defined as a height-for-age below -2 standard deviation (SD) in children under the age of 5 years, is associated with factors such as socioeconomic status, nutrition and household living conditions. Notably, several adverse health and psychosocial consequences can impact future adult health and productivity. Therefore, growth monitoring must serve as an integral component of healthcare delivery for all paediatric patients attending primary care. Family medicine specialists have the privilege of addressing the acute and preventative health care concerns of children and their families. This affords them the unique opportunity to incorporate regular childhood growth monitoring into their practice so that paediatric growth disorders may be identified early.

Understanding normal childhood growth

Growth is an important indicator of health in all children. Healthcare professionals should be familiar with differentiating pathological from normal childhood growth. The process of childhood growth is dynamic and occurs in ‘steps’, with periods of growth punctuated by periods of quiescence rather than the smoothened lines on centile charts. Childhood growth begins in utero during the foetal phase, during which the growth rate is fastest at 60 cm/year. Maternal and uteroplacental health are critical contributors to foetal growth, which ultimately determines the birth weight and length of the newborn. Notably, nutrition is a key regulator of growth in infancy. Psychosocial well-being and an intact thyroid axis facilitate a growth rate of 25 cm/year. During the first 18 months of life, a child’s catch-up or catch-down growth towards their genetic potential is a common observation. Height velocity then decelerates to 10 cm/year during the toddler phase, with nutrition remaining a critical regulator of growth. By 24 months, a child should have shifted towards its genetic potential. Beyond 24 months of age, children grow at a steady rate of 5–6 cm/year and crossing centiles should be considered abnormal. The influences of growth hormone, thyroid hormone and nutrition are important during this phase. With the onset of puberty, the effects of sex steroids and growth hormone accelerate the growth rate to 8–12 cm/year in girls and 10–14 cm/year in boys. Sleep, nutrition and psychosocial health modulate growth hormone release and are crucial in all stages of growth. The interaction of these variables should culminate in the attainment of a final height.
within the mid-parental height centile. Working knowledge of these factors is important to identify the causes of short stature in children. Figure 1 and Table 1 illustrate and summarise the effects of these influencing factors on growth rate in the different phases of childhood growth, respectively.

![Graphical representation of growth rates during childhood and adolescence.]({})

**Table 1. Phases of childhood growth and influencing factors.**

<table>
<thead>
<tr>
<th>Growth phase</th>
<th>Influencing factors</th>
<th>Growth rate (cm/yr.)</th>
<th>Growth pattern</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>In utero</strong></td>
<td>• Intrauterine environment</td>
<td>60 cm/year</td>
<td>Deceleration in growth rate in the first 6 months.</td>
</tr>
<tr>
<td></td>
<td>• Maternal health/size</td>
<td></td>
<td>After 6 months, the growth rate follows a genetic trajectory. Consider if preterm or small for gestational age (SGA).</td>
</tr>
<tr>
<td></td>
<td>• Placental health</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Chromosomal abnormalities</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Infant 0–12 months</strong></td>
<td>• Nutrition</td>
<td>Birth weight (avg.): 3.5 kg</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Environment</td>
<td>Birth length (avg.): 52 cm</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Parental genetics</td>
<td>Growth rate:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Thyroid status</td>
<td>15–25 cm/year</td>
<td></td>
</tr>
<tr>
<td><strong>Toddler 12–24 months</strong></td>
<td>• Nutrition</td>
<td>6–12 cm/year</td>
<td>By 24 months, growth catches up to the genetic target.</td>
</tr>
<tr>
<td></td>
<td>• Environment</td>
<td></td>
<td>Unusual to cross centiles after 24 months.</td>
</tr>
<tr>
<td></td>
<td>• Parental genetics</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Thyroid status</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Pre-school 2–5 years</strong></td>
<td>• Nutrition</td>
<td>Normal growth rate: 7–8 cm/year</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Environment</td>
<td>Abnormal growth rate: &lt;6 cm/year</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Parental genetics</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Thyroid status</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Childhood 5 years to prepubertal</strong></td>
<td>• Growth hormone</td>
<td>Normal growth rate: 5–6 cm/year</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Thyroid status</td>
<td>Abnormal growth rate: &lt;4 cm/year</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Nutrition</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Parental genetics</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Adolescent pubertal</strong></td>
<td>• Sex steroids</td>
<td>Growth rate:</td>
<td>Height at the start of puberty has a major impact on the final height of the child.</td>
</tr>
<tr>
<td></td>
<td>• Growth hormone</td>
<td>Girls: 8–12 cm/year</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Boys: 10–14 cm/year</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Height gained in puberty:</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Girls: 17–22 cm</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Boys: 22–27 cm</td>
<td></td>
</tr>
</tbody>
</table>

Figure 1. Graphical representation of growth rates during childhood and adolescence.11
Definition of short stature

Childhood short stature has several definitions. A static height measurement that is less than -2 standard deviation score SDS (<3rd centile) for that reference population on a sex- and age-appropriate centile chart is considered short stature. A child with a height less than 1.5 SDS (10 cm) compared to mid-parental height (MPH) or the genetic target is another definition. A height velocity (HV) that is <25th centile for age and sex is also considered as poor growth and increases the risk of short stature.

Evaluation of childhood short stature

A comprehensive history, detailed physical exam, accurate anthropometric measurements and growth pattern evaluation are essential for short stature assessment. The history should include details on antenatal growth, perinatal and neonatal events, infant growth pattern, nutrition and the timing of growth faltering. The important elements of history taking for a case of short stature are summarised in Table 2.

Table 2: History taking for childhood short stature.

| Maternal, perinatal and birth history | • Maternal health: diabetes, hypertension, non-organic causes, medications, infections, psychosocial and emotional health, substance abuse |
| • Gestational age, Intrauterine growth retardation, small for gestational age |
| • Hypoglycaemia or jaundice during the neonatal period |
| • Birth weight, length and head circumference |
| Nutrition | • 24-hour food recall or 3-day food diary |
| • Milk intake, breastfeeding, feeding history, snacks, food preference, eating behaviour |
| Medications/ medical/surgical | • Steroids |
| Family history | • Parental heights, pubertal onset, chromosomal abnormalities, severe short stature and investigation, therapy, height outcomes of these family member |
| Review of systems | • Headaches, visual field defects, constitutional symptoms, chronic diarrhoea, recurrent infections, underlying medical conditions, renal symptoms, previous chemo or radiation therapy |
| Social history | • Home and school situation, stressors |
| • Socioeconomic background |
| • Sleep patterns and exercise |

Anthropometric measurements can be single or serial measurements. Although single height measurements are convenient, repeated height measures over time are superior because they are more sensitive to detecting abnormal growth patterns and alert the clinician to potential growth disorders. The accuracy of anthropometric measurements is paramount so that the detection of growth disorders is optimal. This can be achieved by using the appropriate tools such as an infantometer or a stadiometer, where necessary. An infantometer measures recumbent length in children aged 0–2 years. It has three components: a ruler, a fixed headboard and a movable footplate. Notably, it requires two skilled personnel to conduct the measurement. Whilst measuring, the infant’s head should be in line with the Frankfort plane and the legs in full extension. Children over 2 years old should be measured using a wall-mounted calibrated Harpenden stadiometer with a horizontal bar that is fixed at 90 degrees. The child should be standing upright without footwear with the back of their head, buttocks and back touching the wall and with their head in the Frankfort plane. The horizontal bar is then lowered, three sequential measurements are taken and the mean height is recorded. The variation between each measurement should not be greater than 0.3 cm. For repeated measurements to monitor growth over time, it is important to focus on using the correct technique for height measurement by properly positioning the child to obtain accurate results using a reliable measurement tool (e.g., the Harpenden stadiometer, if available). Additional measurements to consider include arm span and sitting height. The correct techniques for using an infantometer and stadiometer are presented in Figure 2.
Figure 2. Infantometer and stadiometer for anthropometric measures in children.15

Anthropometric measurements should be taken opportunistically during unscheduled visits for minor illnesses and during scheduled appointments for routine vaccinations or well-child checks. In the Malaysian setting, the Rekod Kesihatan Bayi dan Kanak-Kanak booklet can serve as a good tool for growth monitoring in infants and children. However, any concerning features or red flags should be evaluated and followed up appropriately. Notably, clinicians should use a single centile chart to monitor serial growth measurements and visualise the growth trajectory.

**Calculations involved in assessing short children**

MPH, MPH target centile and HV are important calculations when assessing short children. Since genetics is a major contributor to the final height of a child, it is critical to calculate the MPH and MPH centile.9 HV can be determined by calculating the difference between height measurements at two time points taken no less than 4 months apart. However, using a 6-month ‘gap’ minimises error. Notably, HV can be plotted on an age- and sex-specific HV centile chart, if available. The ratio between the upper segment and lower segment can help to identify cases of disproportionate short stature. Table 3 presents the MPH and MPH centile calculations. Table 4 summarises the auxology of short children.

**Table 3. Mid-parental height calculations.7**

| For boys, MPH (cm) = (Mother's height + 13 + Father's height) / 2 |
| For girls, MPH (cm) = (Father's height – 13 + Mother's height) / 2 |
| For boys and girls, MPH target height = MPH +/- 10 cm, which represents the 3rd to 97th centiles |

**Table 4. Auxology of short children.9,16**

<table>
<thead>
<tr>
<th>Static height measurements required</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Height more than 2 SDS (3rd percentile) below the mean is severe short stature</td>
<td></td>
</tr>
<tr>
<td>Height more than 1.5 SDS (10 cm) below the calculated MPH</td>
<td></td>
</tr>
</tbody>
</table>

**Growth patterns to assess:**

- HV >1 SDS below the mean AND height more than 2 SDS over 12 months
- Height decrease by more than 0.5 SDS over a 12-month period in children aged 2 years and above
- HV more than 2 SDS (3rd centile) below the mean for a 12-month period if NO short stature present
- HV more than 1.5 SDS below the mean for a 24-month period

**Growth charts**

The use of growth charts is fundamental to the assessment of growth in children. Thus, selecting the appropriate growth chart is paramount. Growth charts can either be standard charts or reference charts—both of which are available in Malaysia. The WHO charts are standard charts, whereas the Centres for Disease Control and Prevention (CDC) charts are reference charts. The difference between these two types of charts is important to note. The WHO standard charts are derived from the longitudinal length and weight data from the WHO Multicentre Growth Reference Study, which recruited 8440 breastfed infants from six different countries. These charts are reflective of how infants should grow and provide a description of physiological growth under optimal feeding conditions.16 The WHO charts can be used for all children, irrespective of ethnicity and type of feeding. The National Centre for Health Statistics (NCHS) and CDC centiles were derived from the National Health And Nutrition Examination Survey (NHANES), which intermittently collated data on the
growth of American children over a 30-year period that started in the 1960s. Thus, the CDC charts describe the growth patterns of a specific population. Within the Association of Southeast Asian Nations (ASEAN) region, national reference growth charts are being used in Singapore and Indonesia. Thai reference growth charts are also in circulation; however, the WHO standard charts are used for growth monitoring. Since there are currently no Malaysian reference growth charts, it is recommended that anthropometric measurements and the MPH of children aged 0–19 years be plotted on a sex-specific WHO standard chart. A syndrome-specific chart should be used where applicable. For infants <24 months, recumbent lengths should only be plotted on a length chart and prematurity should be corrected for all children until the age of 24 months.

**Comprehensive physical examination**

Physical examinations of short children should check for discordance between their height and weight measurements. Albeit rare, endocrine short stature is hallmark by a ‘short and fat’ child whose height is outside the genetic target in association with height deceleration. Midline defects, visual field defects, shortened 4th metacarpals, goitre, striae, and precocious puberty can be indicative of endocrine etiology. Clinical features of disproportionate short stature (e.g., skeletal dysplasias and inborn errors of metabolism) should be sought alongside facies of Down syndrome and Turner syndrome. All short girls must also be examined for other features of Turner syndrome. Moreover, clinical features of chronic disease (e.g., pallor, clubbing, cardiac murmur, hepatomegaly, chronic asthma, or rickets) are also important to examine. Finally, pubertal staging is critical when assessing short children since it may herald a sinister underlying disease process and because pubertal onset in short children requires a prompt referral.

**Table 5. Physical examination of short children**

<table>
<thead>
<tr>
<th><strong>Physical exam findings to elicit</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>• Fat vs thin</td>
</tr>
<tr>
<td>• Proportionate vs disproportionate (short limbs or short spine)</td>
</tr>
<tr>
<td> Sitting and standing heights</td>
</tr>
<tr>
<td>• Features of</td>
</tr>
<tr>
<td>  Syndromes: Down syndrome, Turner syndrome, Russell-Silver syndrome</td>
</tr>
<tr>
<td> Nutritional deficiencies</td>
</tr>
<tr>
<td> Chronic diseases</td>
</tr>
<tr>
<td> Endocrine conditions</td>
</tr>
<tr>
<td> Inborn errors of metabolism</td>
</tr>
<tr>
<td> Skeletal dysplasias</td>
</tr>
<tr>
<td> Central Nervous System examination with fundoscopy</td>
</tr>
<tr>
<td>• Tanner staging of puberty</td>
</tr>
<tr>
<td> Short child in the early stages of puberty</td>
</tr>
<tr>
<td> Sub-optimal growth spurt in puberty</td>
</tr>
</tbody>
</table>

**Causes of short stature in childhood**

As per the European Society of Paediatric Endocrinology (ESPE), there are three categories of short stature: (i) primary growth disorder, in which the condition is intrinsic to the growth plate; (ii) secondary growth disorder, in which the milieu of the growth plate is impacted by a secondary condition; (iii) no identifiable cause, or idiopathic. A more conceptual way of evaluating short stature is to determine whether the short stature is the result of intrinsic shortness, delayed growth, attenuated growth or failure to thrive. Notably, there are no published studies regarding the causes of short stature in Malaysian children. However, the Ministry of Health report on Maternal and Child Health (2016) has noted that stunting in Malaysian children is most common in the following groups: children from certain geographical areas (e.g., Kelantan); children from rural settings; males; those between the ages of 24 and 35 months; those of the ‘Other Bumiputra’ racial background. Table 6 outlines the ESPE classification for short stature.
Table 6. European Society of Paediatric Endocrinology (ESPE) classification for short stature.

<table>
<thead>
<tr>
<th>Classification</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary growth failure</td>
<td></td>
</tr>
<tr>
<td>• Syndromes</td>
<td>Down, Turner, Prader-Willi, Silver-Russell, Noonan</td>
</tr>
<tr>
<td>• Small for gestational age (SGA)</td>
<td></td>
</tr>
<tr>
<td>• Bone dysplasia</td>
<td>Achondroplasia, hypochondroplasia</td>
</tr>
<tr>
<td>Secondary growth failure</td>
<td></td>
</tr>
<tr>
<td>• Endocrine disease</td>
<td>Growth hormone deficiency, hypothyroidism, Cushing syndrome, pituitary deficiency, precocious puberty, poorly controlled Type 1 diabetes, disorders of the GH-IGF-1 axis</td>
</tr>
<tr>
<td>• Inherited metabolic conditions</td>
<td></td>
</tr>
<tr>
<td>• Chronic disease</td>
<td></td>
</tr>
<tr>
<td>• Idiopathic</td>
<td></td>
</tr>
</tbody>
</table>

Approach to the assessment of childhood short stature in primary care and referral

In the primary care setting, the assessment of childhood short stature can be broken down into a few simple steps. It should commence with history taking and a physical examination that focuses on nutrition, chronic disease, endocrine disorders, syndromes and pubertal assessment. Accurate anthropometry with the appropriate tools (i.e., calculations for MPH and HV) should be performed for all children with growth concerns. The objective of first-line investigations is to rule out undiagnosed chronic conditions. If the appropriate resources are available, a karyotype must be conducted for all short girls. A bone age that assesses skeletal maturity—though invaluable in the assessment of short stature—can be performed as a second-tier test. Finally, early referral should be considered if any of the referral criteria is met. In some cases, it may be appropriate to observe growth or involve a nutritionist early on; however, this would depend on the level of concern, the suspected underlying cause and accessibility to allied health services. Rehabilitation services may be indicated in cases where children have difficulty feeding; however, prior assessment by a paediatrician would be required. Figure 3 depicts the general approach to childhood short stature observed in the primary care setting.

Importance of early detection and referral

The age at diagnosis of short stature has a marked impact on the future health and final adult height of a child. This has been observed in several conditions, such as growth hormone deficiency, Turner syndrome and inflammatory bowel disease. In growth hormone deficiency, it has long been demonstrated that early treatment with growth hormone therapy results in superior adult height outcomes. Notably, the age at the start of therapy is negatively correlated with long-term height outcomes. Moreover, adult psychosocial outcomes are also compromised in children with growth hormone deficiency who have delayed detection and treatment. Studies have shown that adults who had delayed growth hormone treatment (i.e., after 12 years of age) had suboptimal adult height, lower educational status, difficulties acquiring employment and social difficulties. This has also been observed in children born small for gestational age. Importantly, the early initiation of growth hormone treatment is reliant on early referrals of short stature. Short stature is the most common feature of Turner syndrome; however, despite this, it is frequently diagnosed late (mean age: 15.1 years). Late diagnosis translates into an increased risk of undiagnosed cardiovascular, autoimmune and puberty-related complications in addition to poor height outcomes. Non-endocrine conditions (e.g., coeliac disease and inflammatory bowel disease), though not necessarily amenable to growth hormone therapy, can adversely impact linear growth, bone health and puberty. The identification of abnormal growth in the early phases of childhood is important since these phases significantly contribute to final adult height. Cumulatively, the data underscores the importance of early detection, referral and treatment of childhood short stature.
**Addressing the problem**

The problem of short stature and stunting in Malaysian children requires serious attention in order to improve health outcomes. The early detection of short stature can be achieved through improved awareness, clinical training and re-certification. Moreover, raising parental awareness about short stature as well as how and when to seek help may potentially lead to earlier detection. There may also be a role for validated high-accuracy growth monitoring applications for parental use (e.g., Growth Journey®), which can serve as a screening tool and alert parents to faltering growth. Finally, a collaborative effort is required to identify and rectify gaps in how early childhood growth monitoring is conducted in Malaysia. At present, growth monitoring from birth until 18 months occurs in tandem with childhood vaccinations, whereas it falls under the purview of the Standard Kecergasan Fizikal Kebangsaan untuk murid sekolah Malaysia (SEGAK) programme for school-aged children. However, there is a gap between 18 months until 7 years of age during which time parents may not attend the recommended well-child visits and maternal child health clinics. This represents a gap during which an opportunity to detect growth disorders is lost. In the developed world, well-child visits are regular health checks that monitor growth, development and provide anticipatory monitoring.

**TIPS**

1. Use appropriate tools for anthropometry
2. Obtain accurate measurements
3. Plot on sex specific/syndrome specific charts
4. Use WHO charts for children 0-18 years
5. Document pubertal staging
6. Repeat measurements 4-6 months apart for height velocity
7. Obtain anthropometric measures at ALL childhood visits
8. Frequency of growth monitoring: in tandem with vaccinations in infancy, 3-6 monthly from 1-4 years, then annually
9. Refer EARLY to a PAEDIATRICIAN or PAEDIATRIC ENDOCRINOLOGIST

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**Figure 3.** Assessment of short children (adapted from 7,13,20).

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Some countries have made school entry health checks mandatory, which are endorsed by their national paediatric association and enforced by the department of education. In other countries, such health checks are voluntary and parents are invited to give informed consent for healthy child checks. In Malaysia, the Ministry of Health Malaysia has endorsed healthy child checks for children aged 18 months to 7 years. Despite this, voluntary attendance by parents remains poor, with only 23.3% of pre-school children aged 5–6 years receiving school health services. In 2017, 75.3% of children aged below 1 year and only 49.5% of toddlers aged 1–4 years received health services from the Ministry of Health Facilities. This identifiable gap raises the question of whether professionals should advocate for a mandatory school entry health check so that paediatric growth disorders—amongst other health conditions—may be detected early.

**Conclusion**
Childhood growth is a dynamic process that is influenced by several factors. Regular growth monitoring with the appropriate tools is essential for the early detection of short stature and stunting and to mitigate its adverse consequences in childhood and adulthood. Future measures should be focused on improving growth monitoring in children prior to school entry. A dedicated dialogue between stakeholders is required to identify gaps and support legislation that may optimise the detection of growth disorders in Malaysian children.

**Statement of funding**
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**How does this paper make a difference to general practice?**
Stunting is a common phenomenon in Malaysian children. Early detection and referral are critical to optimising outcomes for children with stunting or short stature. This review article aims to provide family medicine specialists with a framework on the recommended methods for conducting growth monitoring as well as when and how to make referrals. It also aims to raise awareness about the shortcomings of the existing growth monitoring system in Malaysia and invites readers to consider additional measures that must be considered to further optimise this system.

**Key learning points**
1. Growth in childhood is a dynamic process and provides important information on the general health of a child.
2. Regular growth assessments are critical for the early detection of growth disorders in childhood.
3. Comprehensive history and physical examinations with accurate auxological measurements taken in a standardised manner are the cornerstones of assessing short children.
4. Early referral to a paediatrician is important to ensure that the ‘window of opportunity’ for medical intervention is not missed.

**Key Points**
- Normal growth is a sensitive indicator of child health
- Monitoring child growth is essential at all health visits
- History, anthropometric measures and targeted investigations are critical before considering endocrine conditions
- Early recognition of and intervention in faltering growth are essential to achieving an optimum adult height
References


Barrier to contraceptive use among childbearing age women in rural Indonesia


Keywords:
Barrier, contraceptive, women of childbearing age, rural

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Abstract
Introduction: The contraceptive prevalence rate in Indonesia has not experienced much improvement, which has led to an increase in the number of pregnancies. This study aimed to analyse the barriers to contraception use among women of childbearing age in rural Indonesia.

Methods: This study used a cross-sectional design with data from the Indonesian Demographic and Health Survey (IDHS) of 2017. The independent variables were age, employment status, education, marital status, wealth status, health insurance and parity. The dependent variable was the use of contraception. The statistical significance was set at p <0.05 using bivariate analysis and binary logistic regression.

Results: The study showed that the age group of 45–49 years (OR 0.199; 95% CI 0.149–0.266), secondary education (OR 2.227; 95% CI 2.060–2.514), women married/living with their partner (OR 43.752; 95% CI: 35.484–53.946), wealth status: middle (OR 1.492; 95% CI 1.400–1.589) and multipara (OR 2.524; 95% CI: 2.328–2.737) exhibited the increased use of contraception among women of childbearing age in rural Indonesia.

Conclusion: The variables proven to represent obstacles to contraceptive use among women of childbearing age in rural Indonesia include old age, no education, no husband/partner, poverty and already having one child.

Introduction
Indonesia is a developing country that has population problems. Problems associated with Indonesia’s population include a large population and a high level of population growth. One effort to control this population growth involves the use of a family planning programme. Family planning is a movement that aims to form healthy and prosperous families by limiting or planning the number of children through contraception. Contraception is a method or tool used to prevent pregnancy. Every woman of childbearing age has the right to choose a contraceptive method that works for them. The fundamental essence of reproductive health is to allow women to decide on the number of children they have and when they are born. The use of contraception in women of childbearing age is believed to support quality family formation.

The problem is that the total fertility rate (TFR) in Indonesia has become stagnant over the last three decades. The TFR in Indonesia has reached 2.4 children per woman. This figure remains higher than the target of 2.3 children per woman for the 2015–2019 period. In rural areas, the TFR, general fertility rate and crude birth rate are higher than those in urban areas at 2.6:2 overall and 85:75, 18.5, and 17.5, respectively. Furthermore, the contraceptive prevalence rate (CPR) has not experienced much improvement.

Notably, the CPR fell from 57.6 in 2012 to 57.2 in 2017. This situation led to an increase in the number of pregnancies. The percentage of pregnant women in rural areas (4.1%) was higher than in urban areas (3.7%). Likewise, the percentage of children born in rural areas (3%) was higher than in urban areas (2.6%). Meanwhile, the rate of contraception use (all methods) increased from 27% in 2012 to 34% in 2017. Research on young women in rural areas has reported more obstacles when seeking to access contraception in comparison to urban areas.
The impact of contraceptive failure is an unwanted pregnancy. An unwanted pregnancy is an unhealthy pregnancy that can become a burden for women. Unplanned pregnancies are responsible for 90% of unwanted births. Overall, 17% of these pregnancies are a burden for the women and 89% end in unsafe abortions that threaten women’s welfare. In 2010, the global abortion rate increased from 53 to 56%. In Southeast Asia, it increased from 55 to 59%.

Unintended pregnancies will also increase the number of births.

The use of contraception in rural areas is lower than in urban areas. Moreover, the birth rate in rural areas is higher than in urban areas. The adverse effects of contraceptive failure for fertile women in rural areas are higher than for those in urban areas. Therefore, further analysis of the barriers to rural contraceptive use is required. As such, the present study analyses the barriers to contraception use among women of childbearing age in rural Indonesia. The findings in this study will help family planning policymakers by allowing them to devise strategies to minimise the barriers to contraceptive use for women of childbearing age in Indonesia’s rural areas.

Methods

Study Design
This study used secondary data from the Indonesian Demographic and Health Survey (IDHS) in 2017. The survey was conducted in 34 provinces in Indonesia by the Central Statistics Agency, the National Population and Family Planning Agency, and the Ministry of Health of the Republic of Indonesia. Data collection occurred from July 24 to September 30, 2017.

Sampling Methods
The population consisted of women of childbearing age between 15 and 49 years old in Indonesia’s rural areas. The sampling design used in the 2017 IDHS was stratified using two-stage sampling. Stage 1 involved selecting several census blocks in a systematic probability proportional to size (PPS), with the size of the number of households listed in 2010 population census. In this case, this was systematically performed using an implicit stratification process according to both urban and rural areas and by sorting out the census blocks based on the wealth index category from the SP2010 results. Stage 2 involved systematically selecting 25 households from each census block using the households’ products in each census block. Furthermore, these results were used to identify women of reproductive age that were between 15 and 49 years old. The next selection stage involved selecting women who lived in rural areas. Overall, this process obtained 44,853 respondents.

The 2017 IDHS obtained ethical approval from the National Institute for Health Research and Development of the Indonesian Ministry of Health. All of the respondents’ identities are unknown according to the data and the respondents gave written consent for their involvement in the research. Permission to use the 2017 IDHS in this study was obtained from ICF International on September 27, 2019, through its website (https://dhsprogram.com).

Study Variables
The dependent variable in this study was the use of contraception. The independent variables analysed as potential predictors included age group, employment status, education level, marital status, wealth status, health insurance ownership, and parity.

Measures
In this manuscript, the definition of rural is based on the categories of the Central Bureau of Statistics of Indonesia. The use of contraception is a tool/method used to regulate the time between pregnancies. The use of contraceptives is divided into two categories: use and no use. Contraceptive use includes traditional and modern contraception. The 15–49 years age group was divided into seven groups, with a reference age of 15–19 years. Employment status was split into two groups: working and not working. The reference was that they do not work. Education level consisted of four groups, specifically no education, primary education, secondary education and higher education. Marital status was divided into two groups: married/living with their partner and widowed/divorced/never in a union/no longer living together/separated. Wealth status is a person’s socioeconomic status and describes their wealth level. Wealth level was divided into five groups: poorest, poorer, middle, richer and richest. Health insurance was split into two groups: having and not having health insurance. Parity was the number of deliveries, which was divided into three groups: multipara (2, 3 or 4), grand multipara (4+ labour) and primipara (1 delivery).
Analysis
The first step in data analysis involved testing the relationship using the chi-squared test because all of the variables are dichotomous. In the final stage, the data analysis was performed using binary logistic regression.

Results
Table 1 presents the use of contraception in women of childbearing age in the rural areas of Indonesia. The women of childbearing age who used the most contraception (25.0%) are in the age range of 35–39 years. From the perspective of work status, this was nearly the same since 61.4% of women worked and 61.1% did not work. The use of female contraceptives among those with a primary education totalled 47.0%. The majority of women (99.7%) who were married/lived with their partner used contraception. The wealth status phenomenon found that 51.3% of the poorest women did not use contraception. From the perspective of health insurance ownership, this number was balanced since 38.7% did not use contraception and 38.7% did. Among multiparous women, 70.2% used contraception. Several of the variables related to age, education level, marital status, wealth status and parity show a statistically significant relationship with the use of contraception for women of childbearing age in Indonesia’s rural areas. However, the variables of employment status and health insurance were not proven to have a relationship with contraceptive use.

Table 1. Descriptive statistics of contraception use in women of childbearing age in the rural areas of Indonesia (n = 44853).

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Contraception Use</th>
<th>All</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Age group</td>
<td></td>
<td></td>
<td>&lt; 0.001***</td>
</tr>
<tr>
<td>15–19 (ref.)</td>
<td>93(36.3%)</td>
<td>163(63.7%)</td>
<td>256(0.6%)</td>
</tr>
<tr>
<td>20–24</td>
<td>650(33.0%)</td>
<td>1322(67%)</td>
<td>1972(4.4%)</td>
</tr>
<tr>
<td>25–29</td>
<td>1603(35.1%)</td>
<td>2963(64.9%)</td>
<td>4566(10.2%)</td>
</tr>
<tr>
<td>30–34</td>
<td>2440(32.0%)</td>
<td>5190(68.0%)</td>
<td>7630(17.0%)</td>
</tr>
<tr>
<td>35–39</td>
<td>2926(30.0%)</td>
<td>6830(70.0%)</td>
<td>9756(21.8%)</td>
</tr>
<tr>
<td>40–44</td>
<td>3930(37.8%)</td>
<td>6472(62.2%)</td>
<td>10402(23.2%)</td>
</tr>
<tr>
<td>45–49</td>
<td>5941(55.4%)</td>
<td>4330(44.6%)</td>
<td>10271(22.9%)</td>
</tr>
<tr>
<td>Currently working</td>
<td></td>
<td></td>
<td>0.488</td>
</tr>
<tr>
<td>No (ref.)</td>
<td>6790(39.0%)</td>
<td>10620(61.0%)</td>
<td>17410(38.8%)</td>
</tr>
<tr>
<td>Work</td>
<td>10793(24.1%)</td>
<td>16650(75.9%)</td>
<td>27443(61.2%)</td>
</tr>
<tr>
<td>Education</td>
<td></td>
<td></td>
<td>&lt; 0.001***</td>
</tr>
<tr>
<td>No education (ref.)</td>
<td>1523(65.5%)</td>
<td>802(34.5%)</td>
<td>2325(5.2%)</td>
</tr>
<tr>
<td>Primary</td>
<td>8611(40.2%)</td>
<td>12804(59.8%)</td>
<td>21415(47.7%)</td>
</tr>
<tr>
<td>Secondary</td>
<td>6312(35.1%)</td>
<td>11682(64.9%)</td>
<td>17994(40.1%)</td>
</tr>
<tr>
<td>Higher</td>
<td>1137(44.7%)</td>
<td>1982(55.3%)</td>
<td>3119(7.0%)</td>
</tr>
<tr>
<td>Marital status</td>
<td></td>
<td></td>
<td>&lt; 0.001***</td>
</tr>
<tr>
<td>Married/living with partner</td>
<td>15130(35.8%)</td>
<td>27177(64.2%)</td>
<td>42307(94.3%)</td>
</tr>
<tr>
<td>Widowed/divorced (ref.)</td>
<td>2453(96.3%)</td>
<td>93(3.7%)</td>
<td>2546(5.7%)</td>
</tr>
<tr>
<td>Health Insurance</td>
<td></td>
<td></td>
<td>0.986</td>
</tr>
<tr>
<td>No (ref.)</td>
<td>6798(39.2%)</td>
<td>10541(60.8%)</td>
<td>17339(38.7%)</td>
</tr>
<tr>
<td>Yes</td>
<td>10785(39.2%)</td>
<td>16729(60.8%)</td>
<td>27514(61.3%)</td>
</tr>
<tr>
<td>Parity</td>
<td></td>
<td></td>
<td>&lt; 0.001***</td>
</tr>
<tr>
<td>Primipara (ref.)</td>
<td>1994(48.1%)</td>
<td>2150(51.9%)</td>
<td>4144(9.2%)</td>
</tr>
<tr>
<td>Multipara</td>
<td>9664(33.6%)</td>
<td>19143(66.4%)</td>
<td>28807(64.2%)</td>
</tr>
<tr>
<td>Grand multipara</td>
<td>5925(49.8%)</td>
<td>5977(50.2%)</td>
<td>11902(26.5%)</td>
</tr>
</tbody>
</table>

Note: * p < 0.05; ** p < 0.01; ***p < 0.001.
Table 2. Binary logistic regression for contraception use in women of childbearing age in the rural areas of Indonesia (n = 44853).

<table>
<thead>
<tr>
<th>Determinants</th>
<th>Contraception Use</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Sig.</td>
</tr>
<tr>
<td>Age group: 20–24</td>
<td>0.091</td>
</tr>
<tr>
<td>Age group: 25–29</td>
<td>&lt; 0.001***</td>
</tr>
<tr>
<td>Age group: 30–34</td>
<td>&lt; 0.001***</td>
</tr>
<tr>
<td>Age group: 35–39</td>
<td>&lt; 0.001***</td>
</tr>
<tr>
<td>Age group: 40–44</td>
<td>&lt; 0.001***</td>
</tr>
<tr>
<td>Education: Primary</td>
<td>&lt; 0.001***</td>
</tr>
<tr>
<td>Education: Secondary</td>
<td>&lt; 0.001***</td>
</tr>
<tr>
<td>Education: Higher</td>
<td>&lt; 0.001***</td>
</tr>
<tr>
<td>Marital status: Married/living with partner</td>
<td>&lt; 0.001***</td>
</tr>
<tr>
<td>Wealth status: Poorer</td>
<td>&lt; 0.001***</td>
</tr>
<tr>
<td>Wealth status: Middle</td>
<td>&lt; 0.001***</td>
</tr>
<tr>
<td>Wealth status: Richer</td>
<td>&lt; 0.001***</td>
</tr>
<tr>
<td>Wealth status: Richest</td>
<td>&lt; 0.001***</td>
</tr>
<tr>
<td>Parity: Multipara</td>
<td>&lt; 0.001***</td>
</tr>
<tr>
<td>Parity: Grand multipara</td>
<td>&lt; 0.001***</td>
</tr>
</tbody>
</table>

Note: * p < 0.05; ** p < 0.01; ***p < 0.001.

The statistical test results from using multinomial logistic regression show that the R2 coefficient, which was marked by a Nagelkerke value of 16.1%, indicates that the analysed variables could explain 83.9% of the variability in contraception use. Other factors outside the model can explain the remaining variability. Logistic regression analysis does not require the assumption of linearity between the variables in addition to multivariate normality, homoscedasticity and homogeneity (either dichotomous or multinomial). The categories must be separate from one another and exclusive to allow for the selection of relationships to predict the odds ratio.

Table 2 illustrates the binary logistic regression test results for contraceptive use among women of childbearing age in rural Indonesia. The reference is 'non-user' and the use of contraception in women of childbearing age is as follows. The 45–49 year age group is 0.199 times more likely to use contraception than the 15–19 year age group. Women with a secondary level of education are 2.227 times more likely to use contraception than women who are widowed/divorced. Middle-class women are 1.492 times more likely to use contraception when compared to the poorest women. Multiparous women are 2.524 times more likely to use contraception than primiparous women.

Discussion

Among women of reproductive age in rural Indonesia, the present study indicates that the 15–19 year age group has the highest probability of using contraception. The older the women are, the less likely they are to use contraception. The results of this study are similar to the results of studies examining the use of contraceptives in Nepal, Africa and Nigeria.9,10 These results indicate that the youngest age group is serious about planning/regulating their pregnancy spacing. This could be due to the risk of pregnancy among young women being higher. The risk associated with sexual activity in younger women is higher than that of older women. Data from the Journal of Sexual Medicine suggest that the most sexually active age is 18–29. In the later age groups, the quantity of sexual intercourse decreases.11

Regarding the use of contraceptives, the results of this study differ from those of women in several other countries. Women of Childbearing age in Canada, Ethiopia, North-Western Tanzania, the USA and Nigeria also indicate that contraception use increases with age.12–16 If a woman wants to avoid pregnancy,
contraception is still required—even when the woman is older. For a woman in her reproductive period, increasing age means that she is generally concentrated more on childcare tasks and does not want to have more children.

Differences in the effect of age on contraceptive use in several countries indicate that other factors also play a role in contraceptive use. These factors include culture and beliefs. The diversity of cultures and beliefs in each country is different and will influence women’s decisions to use contraception.

Middle-educated women of reproductive age in rural Indonesia are most likely to use contraception. The less educated a woman of reproductive age is, the less likely she will be to use contraception. This study supports previous findings from Africa, Nepal and Ethiopia.9,10,12,18,19 Education is a planned and formal learning process. A person with more education will be exposed to a lot of scientific information. Moreover, a person’s awareness of their own health needs becomes more prominent if they have better health knowledge. A higher education level among women of childbearing age can be related to more exposure to information about women’s reproductive health.20,21 One of the actions involved in caring for reproductive health is the use of contraception. Thus, it can be understood that higher education increases the interest in maintaining reproductive health by using contraception. Women with a higher level of education tend to discuss contraceptive use with their partners. The result is a joint decision. Decisions resulting from mutual decisions will impact decision satisfaction and result in a higher commitment to contraceptive use.

This study indicates that education increases women’s awareness of responsibly maintaining their reproductive health. Notably, the use of contraception is the result of this awareness. As such, the higher the education level of women, the higher their chance of using contraception.

This study indicates that women of reproductive age in rural Indonesia who are married/living with their partners feel more secure and comfortable in terms of sexual intercourse. This context has an impact on active sexual relations, which can be performed at any time and as often as possible in natural situations. Since every act of sexual intercourse will have the potential for pregnancy, women who are married are more likely to use contraception to adjust their pregnancy spacing.

This study also reinforces the belief that good sexual relations are carried out in a legal marriage. Sexual intercourse that impacts pregnancy can be prevented through the use of contraception. The use of contraception in a legal marriage will perpetuate sexual relations because it can regulate pregnancy spacing.

This study indicates that women of childbearing age and middle wealth status in the rural areas of Indonesia are the most likely to use contraception. Conversely, the poorest women of childbearing age are increasingly not using contraception. These results are in line with findings focused on women of childbearing age in Africa.10,22 Average wealth has a positive and significant effect on the use of modern contraception.23 In light of the various tools and methods possible, the use of contraception costs money. Some contraceptive methods require fees that must be provided continuously every month, three months or 2 to 3 years, whilst others require a one-time fee. However, contraception is not always financed by health insurance. Thus, all women must have a budget allocated for contraceptive use. The richest women are freer to determine their contraception choices according to their health status, whereas the poorest woman must adjust according to their budget.

This study has identified the barriers to contraceptive use for women of reproductive age in rural Indonesia. The highest level of contraceptive use was associated with married and multiparous status. The groups most vulnerable to not using contraception are the 15–19 year age group, the uneducated and the poorest. Additional barriers to contraceptive use in Indonesia include perceptions and the contraceptive services available to women. A study conducted in West Nusa Tenggara, Indonesia showed that...
perceptions regarding the side-effects of contraceptive methods, ease of contraception use and cost of contraceptives relate to the rational pattern of switching contraceptive methods. Notably, a survey performed in Bali, Indonesia found that the utilisation of family planning services was low.

Based on the results of the present study, the most vulnerable groups that require special attention in terms of family planning use in Indonesia are young women who are uneducated and poor. The family-based Indonesia Sehat programme is expected to reduce the disparities in access to contraceptive use. Indonesia’s cultural diversity and territory (i.e., an archipelago) represent challenges for the programme implementers. Community involvement and cooperation between the government and WUS are required to achieve high levels of contraceptive use in Indonesia.

Limitations and Strengths
The principal strength of this study is that it provides policymakers with information about the factors that have become barriers to the use of contraception for women of childbearing age in the rural areas of Indonesia. With its family approach, the Healthy Indonesia Programme is the main programme for health development in Indonesia. Disparities in health development—especially in terms of healthy family indicators—remain present throughout the Indonesian territory. One indicator of a healthy family that requires greater attention is family planning among married women aged 15 to 49 years. Therefore, the use of family planning at the WUS in Indonesia’s rural areas should be a concern. One limitation of this study is that it only focuses on rural women in regions within Indonesia that have archipelagic characteristics and diverse tribes. Therefore, the results cannot be generalised to rural areas in other countries with different demographic characteristics. Moreover, the use of a cross-sectional approach makes it impossible to make conclusions regarding the temporality of the association. Furthermore, this research only focuses on demographic characteristics and does not consider other factors related to the social support systems of women. Therefore, it is necessary to conduct further research on contraception in urban and rural areas by involving determinants related to social support system variables.

Conclusions
Five variables have been identified as barriers to contraception use among women of childbearing age in rural Indonesia. The five factors include old age, no education, no husband/partner, poverty and already having one child.

Acknowledgements
The authors would like to thank the International ICF Institute, which approved the analysis of data from the IDHS 2017. We would also like to thank the Educational Fund Management Agency of the Ministry of Finance of the Republic of Indonesia.

Conflicts of Interest
The authors declare there to be no potential conflicts of interest concerning the research, authorship and publication of this article.

How does this paper make a difference to general practice?

1. This study highlights the strategy and policies of the Healthy Indonesia Programme and suggests that a family approach should be used to target the rural WUS group.
2. This study notes the urgent need for further research and refined policy strategies to ensure that these vulnerable groups can obtain improved access to contraceptive services.
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Unmet basic needs and family functions gaps in diabetes management practice among Indonesian communities with uncontrolled type 2 diabetes: A qualitative study

Rian Adi Pamungkas, Kanitta Chamroonsawasdi, Andi Mayasari Usman


Abstract

Family members play a vital role in both helping and undermining diabetes mellitus self-management practices. This qualitative study aimed to explore the potentially unmet needs of family function to support diabetes self-management (DSM) practices. In-depth interviews and focus group discussions (FGDs) were conducted among different key informants, including uncontrolled T2DM patients, caretakers and healthcare providers (HCPs) at community health centres. An open-ended approach was applied to elicit responses from the key informants. A total of 22 participants were involved in this study. All interview and FGD processes were audio-recorded and transcribed verbatim. The results found that all key informants addressed six core themes, with sub-themes to describe the unmet needs of family function to support DSM practice. The critical unmet needs of family function include: 1) Lack of problem-solving skills to deal with poor diabetes management; 2) Ineffective communication and refusal to share the burden of diabetes management; 3) Lack of affective responsiveness to encourage patients’ compliance; 4) Lack of affective involvement in DSM; 5) Insufficient family roles in supporting patients; 6) Poor behaviour control of T2DM. Our findings provide insights into how family function may influence the adoption and maintenance of healthy behaviours among diabetic patients. Since health providers seek new approaches to improve DSM practices, this valuable finding was essential to understand how family function can improve and empower patients in DSM practice.

Introduction

Uncontrolled type 2 diabetes mellitus (T2DM) has become a significant challenge for Indonesia’s public health system. More than 10 million people in Indonesia were reported to be living with T2DM. Notably, most of them had not met their glycaemic control target goals, which can cause diabetes complications such as neuropathy, nephropathy, retinopathy and cardiovascular disease. Self-management practices are required to control healthy behaviours and prevent severe complications among uncontrolled T2DM patients.

Diabetes self-management (DSM) requires patients to reconcile their resources, values and preferences with a healthy diet, being actively involved in physical activity, avoiding cigarette and alcohol consumption, adhering to medication, monitoring blood glucose levels and preventing diabetes complications. Family members can serve a vital role in helping and reminding patients about their self-management practices. Family function is a fundamental concept linked to providing appropriate tasks that improve the capacity of patients and their family members in dealing with problems, preventing the misinterpretation of emotional responses and maintaining DSM behaviours.

Although several studies have shown the positive effects of family function by involving and supporting patients in achieving positive health outcomes, there remains a research gap in Indonesia regarding how family members should perform the family function to help diabetic patients in their DSM practices. Family members are necessary for DSM practices, especially in lifestyle modification. Also, family members improve patients’ efforts in managing chronic conditions such as diabetes. However, previous studies have not applied the six components of family function.
function theory to support DSM practices. The element of family function is essential and covers all of the patients’ needs. In the rural context of Indonesian communities in West Sulawesi, this study aimed to explore the potentially unmet family function needs of T2DM patients related to supporting DSM practice. The findings from this study should provide a greater understanding of the local community contexts that may influence family function supporting T2DM patients in daily life activities and will also be used as baseline information for healthcare providers to strengthen family involvement in DSM.

Research Questions
1. What is the current situation of family functioning to support T2DM patients in DSM practice?
2. What are the unmet needs of T2DM patients in terms of their family functioning to support DSM?

Literature Review
This literature review covers three main areas: 1) The concept of family function in supporting DSM practice; 2) The daily life contexts of T2DM patients in Indonesian communities; 3) The problems faced by family members when supporting T2DM patients in their DSM practices.

Concept of family function in supporting DSM practice
Family function is classified into two main types: result-oriented and process-oriented. The result-oriented type is also known as Olson’s circumplex model, which defines the family system and divides its role into three features, which include family intimacy (the relationships between family members), family adaptability (changes to the family in terms of its power structure, roles and ability to cope with the external environment) and communication between family members. The process-oriented (also known as McMaster) theory describes family function based on the ability to perform the tasks that families need to complete. The latter concept classifies family function into six basic tasks, which include problem-solving, communication, affective response, family role, family involvement and behaviour control. These were used to explore how family function influenced DSM practices and related to unmet needs since low-income family function could result in poor glycaemic control.

Family function and family roles are not homogeneous. Instead, they are complex and based on family members’ expectations of support for T2DM patients performing their DSM practices. To achieve the positive effects of family members supporting DSM, family members should perform their respective functions to achieve the demands of care for T2DM patients. A previous study applied the notion of family function in supporting DSM practice. In that study, family members’ roles were crucial to assisting the patient in dealing with his crisis. Another study also applied communication skills and family involvement as two parts of the family functioning process in diet management, medication adherence and blood glucose monitoring. Furthermore, an additional study revealed a positive effect of family function in decreasing HbA1c levels. Moreover, another study was conducted to empower family members to support the patients in their DSM. The findings of these studies highlight the positive impact of family empowerment on health outcomes.

In the DSM approach, the use of family function is a positive way to provide appropriate roles and responsibilities for family members in supporting DSM practices. In this study, six dimensions of family function based on McMaster’s family functioning theory were included: 1) problem-solving; 2) communication; 3) affective response; 4) family role; 5) family involvement; 6) behaviour control. These were used to explore how family function influenced DSM practices and related to unmet needs since low-income family function could result in poor glycaemic control. A better understanding of family function could clarify how to help both persons with T2DM and their family members maintain proper DSM to improve glycaemic control.

A previous study focused on family involvement to reduce blood glucose levels among diabetic patients in Indonesia found
that the effective participation of the family caretaker can facilitate proper glycaemic control among T2DM patients.\textsuperscript{22} The present study aimed to apply a family function concept to help patients improve their health outcomes.

**Daily life context of diabetic patients in Indonesian communities**

Indonesia is a patriarchal society. The constructs of culture and religion influence this, with traditions being taught through both formal and informal education. Indonesian people in West Sulawesi follow traditional family lifestyles. These traditional practices are closely linked to the local context of people. Family members play an essential role in decision-making at the household level, especially regarding aspects related to the health of other family members.\textsuperscript{4}

The majority of the Indonesian community still follows the conventional method of sharing meals among all family members. Typically, most of them prepare food by themselves. However, on some traditional occasions, they gather to prepare various types of food and eat together. This situation becomes a challenge for diabetic patients since they must follow their DSM in terms of dietary control.

**Problems related to family members supporting T2DM patients in their DSM practices**

Family members serve essential roles in promoting healthy lifestyle behaviours and appropriate emotional responses, sharing feelings and supporting sustained DSM practices. However, in certain situations, family members believe that their lifestyle changes should depend on their own decisions due to difficulties related to sharing knowledge on diabetic control with their family.\textsuperscript{23} Although some families support patients in their DSM practices, they often sabotage or undermine patients’ self-care efforts by providing unhealthy meals and tempting patients to eat sweets as a reward they fully comply with their medications.\textsuperscript{24} These actions may become harmful and often conflict with established family routines. Therefore, to achieve optimal DSM practices without harm and conflict, a family-based approach is required for this population. This study aimed to improve health service delivery by applying the effective management of DSM practices through involving family members as critical support for glycaemic control among T2DM patients.

**Material and Methods**

**Study design**

Qualitative research using a phenomenological study was conducted to explain and interpret the meanings of individual experiences based on perspectives and perceptions within the local context.\textsuperscript{25} T2DM patients were a primary source of data collection. More specifically, the data include the meanings and perceptions of the key informants regarding their family functioning to support DSM practice. Furthermore, the unmet needs of T2DM patients due to poor family function, problems and challenges in daily activities were also collected. A wide range of themes and sub-themes were related to the unmet family function needs of these patients. For different perspectives, insufficient family roles in DSM practices among low-income families, the patients, their caretakers and their healthcare providers (HCPs) were also added. This study represents the preliminary phase of a sequential exploratory mixed-method design to explore the current situation of DSM practices and family function in supporting T2DM patients in glycaemic control. The findings were used to design intervention activities to strengthen the family function in the later phase.

**Study setting**

The qualitative study was conducted between 1st January and 28th February 2019 at the community health centre located in Polewali Mandar District, West Sulawesi, Indonesia. This community health centre provides essential services to communities, including medical facilities, immunisation, geriatric services and endocrinology.

**Samples and inclusion criteria**

The triangulation method was used to explore data from different viewpoints among patients, family caretakers and HCPs. The triangulation method is widely used in qualitative studies\textsuperscript{26} to assemble an aggregation of data collected from different sources or the different viewpoints of key informants to validate the findings’ truth. Also, multiple data collection methods and the use of different perspectives among the researchers in data analysis can be used to gain a greater understanding of a particular phenomenon.

A total of 22 key informants were recruited based on the inclusion criteria. These included
eight uncontrolled T2DM patients, eight family caretakers and six HCPs.

As the primary key informants, the patients were recruited from the Prolanis members of the diabetes control programme at the community health centre. This programme was launched in Indonesian communities to promote effective diabetic prevention and control via regular home visits performed by HCPs to monitor DSM and blood glucose. The inclusion criteria were as follows: 1) Uncontrolled T2DM with an HbA1c level >6.5%; 2) ≥35 years of age; 3) Has been living with T2DM for at least 2 consecutive years; 4) Able to communicate in the Indonesian language and willing to share ideas and experiences via an in-depth interview process. The patients were excluded if they had severe complications that required hospitalisation. Before data collection, the research team conducted a meeting with the HCPs at the community health centres to explain the data collection objective. Then, the primary key informant group was recruited and the researcher made appointments to visit each patient in their home for an in-depth interview. Among the primary key informants, 12 were recruited from six communities. Overall, eight informants agreed to participate in the in-depth interview process after informed consent was obtained. The second key informant group comprised the caretakers directly related to T2DM patients, which consisted of either the wife, husband, daughter or son responsible for serving as the primary caretaker and supporting the patient in daily life activities and DSM practices. The selection of caretakers was performed in parallel with the T2DM patients after providing a clear explanation of the study objectives. Family members were excluded if they had no experience in taking care of patients with diabetes mellitus, were unwilling to participate in this study or were not living in the same house as the patients.

The inclusion criteria for the HCPs included those whose role was to provide diabetes care and support at the community health centre and those who had worked in this area for at least 1 year. We recruited one HCP from each of the six different community health centres in Polewali Mandar District. Before the in-depth interviews and focus group discussions (FGD) were carried out, informed consent was obtained and the confidentiality of information was clarified. Moreover, the presentation of our findings would not directly outline the personal information of each key informant.

The main themes were developed based on the six aspects of family functioning theory: 1) Problem-solving related to improper DSM practice; 2) Effective communication to strengthen DSM practices and remind patients about blood glucose monitoring and medication adherence; 3) Affective response through empathy and sharing love and care; 4) The family role providing support in DSM practices (e.g., providing healthy food, accompanying patients for doctor visits and encouraging patients to exercise); 5) Family involvement in daily activities for glycaemic control; 6) Behavioural control of the patients to promote the reduced consumption of sweets and unhealthy food, adherence to the medication and monitoring of blood glucose.

Details regarding the key informants, data collection methods and data collection themes based on the triangulation method are summarised in Table 1.

**Table 1. Description of samples based on the triangulation method.**

<table>
<thead>
<tr>
<th>Participants</th>
<th>Methods</th>
<th>Themes</th>
</tr>
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</table>
| Uncontrolled T2DM patients (n=8) | In-depth interview | • Perception of family function support and unmet needs in DSM practices from caretakers  
• Challenges and obstacles of patients in performing DSM practices |
| Family caretakers (n=8)    | In-depth interview | • Family function to support patients in their DSM practices  
• Challenges and obstacles to supporting patients in their DSM practices |
| Healthcare providers (n=6) | Focus group discussion | • Implementation of existing services to support patients and their families in DSM practices at the community level |
Data collection procedure

The researcher and research assistants were trained on the qualitative method of data collection and the roles of note-taking and tape-recording. In-depth interviews and FGDs were conducted using a semi-structured interview format with open-ended questions and followed an interview guideline based on the main themes and sub-themes to elaborate the information based on their viewpoint. Each interview was conducted for approximately 60 to 90 minutes in a private room. Before conducting in-depth interviews and FGDs, all participants signed an informed consent form. The researchers also kept participants identities confidential to ensure privacy.

All data were audio-recorded and transcribed verbatim by two researchers. The interview guideline included the following themes: 'background information', 'unmet need in family function perceived by T2DM patients', 'family function to support DSM practice', 'responsibilities in diabetes management', 'challenges in DSM' and 'challenges in supporting T2DM patients in DSM'. The interview guideline was developed by researchers based on the concept of family function and the DSM model. Then, each question was checked by three experts to ensure the content validity of the interview guidelines. Inappropriate questions were modified by the researchers based on the experts' suggestions. A pilot test was also conducted among three uncontrolled T2DM patients and three caretakers from the same families as the patients.

Bracketing interviews were conducted prior to, during and following the data collection process to uncover themes and sub-themes that may hinder the researcher's ability to listen to the respondents or trigger emotional responses amongst participants while interviewing with the researcher. These were also used to clarify the key informants' experiences by exploring their forgotten or recalled experiences.

Two researchers analysed the data saturation after all data were transcribed from the audio recording to the answer sheet. The involvement of participants was required to check the transcripts of the interviews. All information from the key informants that represented a new viewpoint was triangulated by comparing the critical point or information. Two researchers extracted and quoted key themes and sub-themes from different data sources in parallel to reach a consensus on the findings.

Comprehensive data management is crucial to protecting the study participants. In this process, we defined data boundaries and protections that adhere to ethical standards while prioritising data dissemination. Dissemination of the results rests upon the ability to collectively determine how, where and to whom a team would like to communicate the results. In this process, we selected salient themes, which were then analysed and reported on through descriptions of the aggregated data in the local contexts.

To address credibility, the researchers attempted to reveal an accurate picture of the phenomenon under scrutiny. To facilitate transferability, we provided sufficient details regarding the fieldwork contexts to decide whether the prevailing environment was similar to another situation. Finally, to achieve confirmability, the researchers took steps to demonstrate that findings emerged from the data and not their predispositions.

Data analysis

The data were transcribed and provided verbatim from the audio recordings. Two researchers reviewed and read each transcript and grouped the interpretations and meanings from their emic viewpoint into main themes and sub-themes to elaborate the phenomena. The summary of the transcript was scripted to track the different key themes. The final step in this qualitative data analysis was to summarise the categories of critical themes and sub-themes based on each group of key informants' viewpoints.

Ethical considerations

We obtained informed consent from all participants who were willing to participate in this study. The Ethical Review Committee for Human Research, Faculty of Public Health, Mahidol University approved this study (number: MUPH 2018-173). A permission letter from the head of each community health centre was also obtained before conducting this study.

Results

Demographic characteristics

We recruited and interviewed eight uncontrolled T2DM patients. The average patient age was 45 years. Out of eight patients, three were male and five were female. Their duration of illness ranged from 2 to 7 years. Some T2DM patients received support from their spouse, daughter
Seven of the family members included in this study were female and one was male. Most of the family members had completed high school and received a bachelor’s degree.

Most of the HCPs that participated in this study were female. Three of them had completed a level II diploma in nursing, whilst the other three had graduated with a bachelor’s degree. The HCPs had been working in the Prolanis programme, which mainly responded to the diabetes care units at community health centres.

**Diabetes mellitus self-management practices**

Within the community health centre, diabetes management has primarily occurred in the form of primary healthcare services. Patients with diabetes mellitus were required to perform healthy behaviours to control blood glucose levels. However, some barriers to DSM were identified among the T2DM patients, such as unhealthy eating habits, a lack of physical activity, loss to follow-ups, and a lack of blood glucose monitoring.

Some barriers within the key informants’ families regarding the support of diabetes self-management practices also existed. Conflict within the family also became a barrier to effective DSM practice. For example, they separated food for the patients during meals with other family members. Moreover, the family members sometimes sabotaged the patients by being strict about food, which caused some conflicts within the family. Therefore, exploring the needs of the patients regarding their DSM practices was a crucial point in this study.

**Unmet needs of family functioning to support diabetes mellitus self-management practices**

Following the components of family function, the unmet needs of T2DM patients in terms of family functioning to support diabetes mellitus self-management (DMSM) practices were systematically described by the low-income family function, which could not serve their needs in DMSM practices. This was categorised into the following themes:

1. **Lack of problem-solving skills to deal with poor diabetes management**

Five patients lacked decision-making skills to deal with problems that occurred whilst maintaining their DMSM practices. Some patients revealed that their caretakers did nothing to help them think about the problem because they lacked an understanding of diabetes and its management. Additionally, the caretakers also lacked critical thinking and problem-solving skills when faced with the poor self-management of T2DM patients. Other patients mentioned that they lacked skill and support and had personal conflicts with family members, especially when family members asked them to avoid unhealthy food.

’If I am feeling stressed and having difficulty falling asleep at night, my husband tries to support me—but it is difficult to do’ (Patient no. 2, female, 41 years old).

’Sometimes we have conflicts when she forbids me from eating certain foods, such as meatballs and soft drinks’ (Patient no. 8, male, 55 years old).

Five family members also expressed some difficulties related to solving patients’ problems. Some of them did nothing when patients faced the problem of uncontrolled glycaemia. Notably, some family members mentioned their conflicts with patients when they asked them to avoid junk food, reduce fatty and sweet food intake and recognise their portion size.

’I sometimes advise and help them to control the diet of my husband, but he always conflicts with me when I forbid him from eating certain foods. I do nothing when my husband is angry with me’ (Wife, 50 years old).

Three HCPs reported that most caretakers do not understand how to care for patients with T2DM and lack the skills required to support patients in coping with diabetes. They also mentioned that caretakers lacked skills for dealing with patients’ problems and were unclear about early detection and how to help patients when they complain about their condition.

’Some of the family members lack the knowledge and skills needed to care for their families, and they also experienced difficulty in helping patients when they complain about their disease’ (HCP no. 1, female, 30 years old).
2. Ineffective communication and refusal to share the burden of diabetes management

Four patients mentioned a lack of effective communication with their families about diabetes and its management. One patient discussed daily activities rather than a discussion about their diabetes and health condition. Another patient said that she rarely discussed it with her husband since he was busy working. Two patients expressed the same event of not consulting their families because they should take care of themselves.

‘I rarely communicate with my husband about my disease because I should be responsible for my body’ (Patient no. 2, female, 41 years old).

‘Almost every day, my husband goes to work. So, I rarely communicate or discuss my condition’ (Patient no. 5, female, 63 years old).

Some family members also reported a lack of positive communication with patients. They refused to share the burden with the patients and discouraged patients from discussing their problems. One family member said that she gave a patient money to check their blood glucose and visit the community health centre for follow-up treatment due to a lack of time to take care of and accompany the patient to see the doctor. Other family members expressed their negative feelings when discussing diabetes with family members because there were some conflicts.

‘I seldom communicate with my wife about the disease. However, I just give her money when she needs to check her blood glucose at Puskesmas’ (Husband, 63 years old).

3. Lack of affective responsiveness to encourage patients’ compliance

Five patients reported that they received inadequate responses to their conditions. Both patients and their caretakers often had personal conflicts, whilst the caretakers felt unhappy and angry when the patients ignored their advice.

‘We often have a conflict between us because she cooks food without tasting it and sometimes my family gets angry with me when I complain about that food’ (Patient no. 8, male, 55 years old).

One family member remained silent whilst ignoring and discouraging a patient from discussing her condition. One spouse prepared unhealthy food and expressed irritation and doubt about food choices.

‘Sometimes I don’t care about the patient when he does not follow my advice and feel discouragement because he refuses my suggestions and the doctor’s advice’ (Wife, 50 years old).

4. Lack of affective involvement in diabetes management

Three patients managed their self-management practices without their families becoming involved. One patient said that her husband just provided some money without affecting the diabetes management process. The two remaining patients also mentioned that they managed their diet by themselves because their family members were not free and had to work every day.

‘The decisions regarding my treatment are dependent on me; I manage everything by myself. My husband just gives me money when I need to do a check-up at the hospital’ (Patient no. 3, female, 55 years old).

‘I always prepare my menu by myself since my family must go out to work’ (Patient no. 8, male, 55 years old).

Contrary to other family members’ perspectives on managing diabetes, treatment should be the responsibility of the patient. Another family member said although he was not involved in the patient’s treatment plan, he supported its financial needs. One family member mentioned that the patient was more active in seeking diabetes information, so he only provided some money to address the patient’s needs. Also, another family member expressed her feelings about conflicts with the patient when discussing diabetes and its management, which ultimately led her to ignore it.

‘My wife is more active in seeking information regarding diabetes management. I just provided some money’ (Husband, 63 years old).
‘Sometimes, I have conflicts with my husband when discussing diabetes and its management. Therefore, I ignore my husband when he is angry with me’ (Wife, 50 years old).

Some HCPs mentioned that most patients come to community health centres for health check-ups without family members. They come for routine blood glucose monitoring and sometimes join a group for aerobic exercise.

‘I have seen many patients come to community health centres alone for routine blood glucose level checks. They also join aerobic exercises, take medication and receive education in Puskesmas’ (HCP no. 6, female, 35 years old).

5. Insufficient family roles in supporting the patients

Five patients said that they find it difficult to solve problems and receive suboptimal support from their family members. Some patients solve issues by themselves since family members do not understand diabetes and its self-management. In contrast, one patient experienced conflict whilst implementing DMSM practices. Other patients expressed their feelings regarding difficulties they faced in managing portion size, avoiding sweet and fatty foods and preparing healthy food to eat without any support from their relatives.

‘I have had difficulty controlling my diet, especially when attending some special occasions. I ate all kinds of food—my husband was not worried about that’ (Patient no. 3, female, 55 years old).

‘When I become bored, my family allows me to eat all kinds of food’ (Patient no. 3, female, 41 years old).

Two family members said that they sometimes had conflicts with the patients because they did not follow the dietary control menu plan for T2DM. Moreover, patients faced challenges when attempting to follow the dietary regimen since they always ordered food from a restaurant.

‘We have difficulties in controlling food because we often order food from the restaurant’ (Family member, male, 55 years old).

6. Poor behaviour control

Most patients faced some difficulties in controlling their behaviours. They felt dull and uncomfortable, especially in certain conditions or when staying away from home.

‘I face difficulty in controlling my diet, especially when attending wedding ceremonies’ (Patient no. 1, female, 48 years old).

‘My wife never reminds me to control my diet when I am far away from home’ (Patient no. 8, male, 55 years old).

This is inconsistent with family members’ perceptions of difficulties in controlling blood glucose levels when they were not staying with the patients. Some of them reminded the patients to be aware of accidents due to falling when wearing slippers and how to wear comfortable slippers to prevent foot ulcers.

‘I am trying to control my mom’s blood glucose level but finding it challenging, especially during special occasions. I always suggest that she maintains her blood glucose level, but she is bored of doing it (Family member, female, 38 years old).

‘I face difficulty in controlling my husband’s diet when he is far away from home. I often remind him to take care of his foot ulcer by using comfortable slippers (Family member, female, 45 years old).

One healthcare provider mentioned that most patients and their family members faced difficulty in maintaining blood glucose levels within the normal range, especially when they did not follow advice from healthcare providers regarding a healthy diet and regular exercise.

‘When I interview some patients and their caretakers, most of them find it difficult to control and maintain blood glucose in the normal range. Their blood sugar is unstable and sometimes higher than normal, especially when ignoring diet and inactive physical activity’ (HCP no. 2, male, 34 years old).

Table 2 summarises the unmet needs of family function in supporting DMSM practices. Six themes were identified from this
study: 1) Lack of problem-solving skills to deal with poor diabetes management; 2) Ineffective communication and refusal to share the burden of diabetes management; 3) Discouragement and feeling irritation about patients’ compliance; 4) Uninvolved in decisions related to diabetes management; 5) Insufficient family roles in supporting patients; 6) Inconsistent management of healthy behaviour during special occasions.

### Table 2. Unmet needs of family function in DMSM practices.

<table>
<thead>
<tr>
<th>Themes</th>
<th>Sub-themes</th>
<th>Sources</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lack of problem-solving skills to deal with poor diabetes management</td>
<td>• Lack of knowledge and skills to solve the problems</td>
<td>• Patients</td>
</tr>
<tr>
<td></td>
<td>• Conflict between the patients and caretakers</td>
<td>• Family caretakers</td>
</tr>
<tr>
<td></td>
<td>• Obstacles to providing family functions to support DSM practices</td>
<td></td>
</tr>
<tr>
<td>Ineffective communication and refusal to share the burden of diabetes management</td>
<td>• Poor communication to support DSM practices from the family</td>
<td>• Patients</td>
</tr>
<tr>
<td></td>
<td>• Discouragement and feeling inadequate about communicating and discussing with family</td>
<td>• Family caretakers</td>
</tr>
<tr>
<td></td>
<td>• Lack of time to perform positive communication</td>
<td></td>
</tr>
<tr>
<td>Lack of affective responsiveness to encourage patient compliance</td>
<td>• Self-management practices without family support</td>
<td>• Patients</td>
</tr>
<tr>
<td></td>
<td>• Refraining from involvement in supporting patients with DSM</td>
<td>• Family caretakers</td>
</tr>
<tr>
<td></td>
<td>• Poor judgement related to DSM since patients are responsible for taking care of themselves</td>
<td></td>
</tr>
<tr>
<td>Insufficient family roles in supporting patients</td>
<td>• Insufficient family support on healthy behaviours</td>
<td>• Patients</td>
</tr>
<tr>
<td></td>
<td>• Feeling difficulties in managing a healthy diet</td>
<td>• Family caretakers</td>
</tr>
<tr>
<td></td>
<td>• Conflict with patients on dealing with diet control</td>
<td></td>
</tr>
<tr>
<td>Poor behaviour control</td>
<td>• Unable to control when far away from home</td>
<td>• Patients</td>
</tr>
<tr>
<td></td>
<td>• Not following advice from healthcare providers</td>
<td>• Family caretakers</td>
</tr>
</tbody>
</table>

### Challenges and obstacles in the provision of diabetes mellitus self-management education in the community (information obtained from HCPs)

The challenges and obstacles noted by HCPs in providing diabetes mellitus self-management education (DMSE) at the community health centre are categorised into themes, as follows:

1. **Lack of skills in providing DMSE**
   
   During the FGD process, some HCPs confirmed a lack of experience and some misunderstandings related to DSM practices. Some challenges related to providing DMSE to diabetes patients in the community were noted. For example, there was a lack of educational media to deliver information on DSM, whilst DMSE was provided using one-way teaching rather than counselling or participatory learning. Another HCP noted that they delivered the information and education every week without any evaluation forms to track the behavioural changes of patients after receiving the DMSE programme.

2. **Insufficient manpower**

   Some HCPs mentioned that they spend a long time intensely working on administrative tasks at the community health centre. They also mentioned that they provide approximately 8 hours of treatment and care for hospitalised patients. Some of them also reported that they had to perform other jobs related to disease prevention and control in the community, such as providing child immunisation, tuberculosis control and communicable disease surveillance due to a limited number of HCPs. They also had to refer patients to the provincial hospital when an emergency requiring the further management of patients’ symptoms occurs. The challenges and obstacles highlighted by the HCPs in providing DMSE to support the DSM of T2DM patients are summarised in Table 3.
Table 3. Challenges and obstacles among HCPs in providing DMSE to support DSM.

<table>
<thead>
<tr>
<th>Themes</th>
<th>Sub-themes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lack of problem-solving skills to deal with poor diabetes management</td>
<td>• Limited educational media and booklets&lt;br&gt;• One-way teaching of DMSE</td>
</tr>
<tr>
<td>Insufficient manpower</td>
<td>• High workload and job demands in the community prevention and control programme&lt;br&gt;• Lack of confidence and experience in dealing with diabetes management</td>
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Discussion
In this study, we determined how the unmet family function needs of T2DM patients cause impaired family function in supporting DSM practices. Family members have an essential role in supporting DSM practices through how they engage in behavioural change, increase communication skills, set goals, solve problems and influence patients’ efforts. By using thematic analysis, we identified all of the unmet family function needs related to DSM practices. Our findings provide valuable evidence regardless of family functioning’s usefulness in supporting behavioural changes towards optimal T2DM self-management. Notably, previous studies have described the importance of the supportive and non-supportive actions of family in maintaining behaviours.10, 27-29

Problem-solving skills are crucial for both patients and caretakers in dealing with DSM practices. Lack of knowledge and skill are fundamental factors that prohibit families’ critical thinking abilities when attempting to solve problems or enhance their problem-solving skills to support patients in their DSM practices. Previous studies have revealed that problem-solving skill was related to dietary self-management behaviours, exercise patterns and psychosocial measures.30,31 Another study showed that problem-solving based DSM practices were sufficient to improve behaviour among lower-income patients.32

Successful diabetes management requires good teamwork between patients, caretakers and healthcare providers. Effective communication on DSM and sharing decision-making in diabetes care might impact treatment plans and health outcomes. Notably, poor communication has been associated with misconceptions related to diabetes management.19 Likewise, effective communication was shown to have a positive effect on improving patients’ understanding and influencing self-management skills.33

Furthermore, the negative responses of family members can affect DSM practices. The present study showed that family members were silent and discouraged patients from discussing their conditions. Moreover, a previous study showed that some patients tend to avoid expressing their needs due to the negative responses of family members, especially regarding eating behaviours and unhealthy lifestyle choices59. Another study also reported that poor support from family members was associated with poor glycaemic control and health outcomes during the implementation of DSM practices.54

Family involvement was a crucial aspect of maintaining DSM practices. Patients who lacked emotional support often had poor relationships with their family members, especially their spouses.55 The same study also reported that family involvement in the DSM and glycaemic control of diabetic patients is essential.54

Family and social support can predict health-promoting behaviours and improve health outcomes among uncontrolled T2DM patients. A previous study revealed a positive correlation between social support and treatment adherence, with social support buffering patients’ stress when living with a chronic illness such as diabetes.56 Another study also noted a positive correlation between optimal social support and self-care behaviour. Therefore, receiving sufficient support from family members can be a significant issue, which highlights the responsibility of family members in improving diabetes management.57 One notable barrier to diabetes care was the inaccessibility of a healthy diet and physical exercise when away from home. This challenge can impact the maintenance of healthy behaviours among uncontrolled T2DM patients. This study also confirmed a cause of unmet family function needs related to supporting DSM practices: the inability to control patients’ behaviours when they are
away from home. Notably, both patients and their caretakers found it challenging to achieve the patients’ blood glucose target.

Our results also contribute to understanding the complexity of family function. One obstacle to DMSM practices is that some determinants cannot be seen to have positive or negative effects. However, these are essential to consider within the community’s socio-cultural context. The potential aspect of leveraging family function aims to improve DMSM practices by helping family members understand their DMSM support roles. These roles include diet control as well as support in physical activity, medication taking, blood glucose monitoring, the prevention of diabetes risk complications and emotional support when facing stress related to the diabetes prognosis. It is important to note that family members should clarify their roles and functions to support T2DM patients in effectively managing diabetes according to the local situation and context of DMSM in communities.

Strengths and Limitations
This preliminary study is culturally explored from the perspectives of two Indonesian ethnicities in one province. We emphasised cultural information from the perspectives of T2DM patients, their families and HCPs during the data collection process by following the societies’ local contexts and habits. Although the data were collected from different groups, the results cannot be generalised to explain the unmet family function needs of all diabetic patients in Indonesia. Moreover, the community perspective was not considered, which may affect the generalisation of these results to other communities.

Implications for Practice
The findings of this study suggest that HCPs at community health centres should involve family members in fully supporting T2DM patients in their DMSM practices. A group-based training with participatory learning and sharing experiences should be conducted among patient-caretaker dyads to strengthen family function and help patients in their daily life activities.

Conclusion
The findings of this study help to provide a better understanding of the context of family function in supporting patients in their DMSM practices. We also explored the unmet DMS support needs of patients, which including a lack of problem-solving skills for dealing with poor diabetes management, ineffective communication and refusal to share the burden of diabetes management, lack of affective responsiveness in encouraging patients’ compliance, lack of affective involvement in diabetes management, insufficient family roles in supporting patients, poor behaviour control and insufficient family roles to support patients, and the inconsistent management of healthy behaviour during special occasions. HCPs should consider patients’ needs and how best to support diabetic patients and their families. As such, an intervention that considers the cultural context of Indonesian communities is required.

Acknowledgements
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Conflicts of Interest
We declare no conflicts of interest to publish this manuscript.

Author Contributions
RAP and KC designed the research and performed the conceptualisation, data collection, data analysis and writing of the original draft.

References


The association between body mass index and the oral Firmicutes and Bacteroidetes profiles of healthy individuals

Roshna Mohamed Qadir, Mahde Saleh Assafi


Keywords:
Obesity, oral bacteria, firmicutes, bacteroidetes, Iraq

Abstract

Introduction: Microbiome status is considered an important factor that contributes to obesity. Investigations have shown that the oral microbiome comprises a vast array of bacterial species that can influence human health.

Objective: To determine the association between the presence of the bacterial phyla Firmicutes and Bacteroidetes and the body mass index (BMI) status of normal, overweight and obese subjects in Duhok, Iraq. Additionally, to investigate the composition of oral Firmicutes and Bacteroidetes profiles for individuals with different BMI statuses.

Methods: A total of 155 saliva samples were collected from participants in Duhok, Iraq. Bacterial genomic DNA was then extracted from the collected saliva. The presence of Firmicutes and Bacteroidetes phyla was detected via polymerase chain reaction.

Results: Firmicutes and Bacteroidetes were detected in 63.2 and 37.4% of the population, respectively. Differences in the carriage rates of oral Firmicutes in overweight (78%) and obese individuals (83%) were statistically significant when compared to normal weight individuals (36%) (P<0.0001). The percentage rates of Bacteroidetes in obese individuals (26.4%) was statistically significant when compared to normal weight individuals (50.8%) (P=0.0078). The Firmicutes/Bacteroidetes ratios (obese=3.1, overweight=2.5 and normal weight=0.7) were higher with increasing BMI.

Conclusion: This study provides evidence of the Firmicutes/Bacteroidetes ratio growing with increasing BMI. High rates of Firmicutes could serve a role in the development of obesity. Further studies are required to clarify the exact relationship between oral bacteria and obesity, which could lead to a promising therapeutic method for improving the physical health of humans.

Introduction

Obesity rates are increasing among people worldwide.\(^1\)\(^2\) In Europe, the prevalence of obesity has risen from 10 to 40% in the last 10 years.\(^3\) At the simplest level, obesity is a change in the natural energy balance that can lead to an increase in energy consumption and excess fat accumulation in the body. Thus, it can have a negative impact on health and is associated with early mortality, which contributes to significant medical and social costs.\(^4\) Several studies have been conducted to identify the main factors contributing to obesity development.\(^5\) The interaction between genetics and the environment is the result of complex pathological adaptations by cells in the human body and represents the most crucial factor contributing to obesity.\(^5\) There are several pathophysiological mechanisms behind systemic metabolic dysfunctions. Mechanisms that contribute to obesity include insulin resistance, hypertension and dyslipidaemia.\(^7\) In the past decade, the association between the microbiome and the increased risk of obesity has received considerable attention.\(^8\) The gut contains bacteria belonging to the phyla Firmicutes, Bacteroidetes, Proteobacteria and Actinobacteria. According to recent studies, Firmicutes and Bacteroidetes mainly disturb human nutrition and metabolism.\(^9\) Studies of human gut microbiota in obese individuals have shown that the guts of obese individuals had a higher ratio of Firmicutes to Bacteroidetes (F/B).\(^10\) However, several studies failed to observe a significant alteration in the F/B ratio between normal weight and obese individuals.\(^11\)\(^12\)

Although most studies have focused on intestinal microbiota, all gastrointestinal bacteria enter through the oral cavity, with some of these transients localising there.\(^13\) The
oral microbiome serves a role in the occurrence of various diseases in humans and is composed of a vast array of bacterial species that interact in complex ways. In 2009, the first association between the oral microbiome and obesity was highlighted. Further investigations have shown differences in the oral microbiome compositions of obese individuals. It was found that the salivary microbiome has a higher phylogenetic diversity in obese individuals. Iraq has obesity rates of approximately 8% in males and 19% in females. However, there are no data related to obesity and the oral microbiome in Iraq. Hence, the present study aimed to assess and analyse differences in the composition of oral Firmicutes and Bacteroidetes phyla among individuals with different body mass indexes (BMIs) in Duhok city, Kurdistan Region, Iraq by using a molecular approach.

Methods

Study Design and Sample Collection
The present study was conducted between September 2018 and September 2019 in Duhok, Kurdistan Region, Iraq. A total of 155 saliva samples were collected from adult participants (69 males and 86 females) aged between 19–35 years. All participants completed a brief questionnaire and were then tested for their BMI. Based on the World Health Organization guidelines, participants were grouped into three categories according to their BMI. These categories include normal weight individuals (BMI 18.5–24.9 kg/m²), overweight individuals (BMI 25.0–29.9 kg/m²) and obese individuals (BMI ≥30.0 kg/m²).

Before sampling (between 9:00 and 11:00 am), participants refrained from drinking and eating, and the mouth was rinsed with water to remove any food residue. After 10 min, 5 ml of unstimulated whole saliva was collected in a 50 mL DNA-free sterile container and then transported to a laboratory for further investigation. The exclusion criteria were severe periodontal destruction, the existence of any systemic disease, use of medications, smoking, pregnancy/lactation, not using antibiotics (the last 3 months), any chronic illness (e.g., psychiatric disorders, anorexia, acute relapse, etc.). Also, individuals with an inadequate quantity (<2 mL) or insufficient quality (concentrated) of saliva were excluded.

Genomic DNA Extraction
Bacterial genomic DNA was extracted from human saliva samples using a commercial DNA purification kit (A1620) (Promega, Germany), according to the manufacturer’s recommendations. Briefly, 2 ml of saliva sample was centrifuged at 16,000 x g for 2 min, and the pellet was suspended in 480 μl of 50 mM EDTA. Then, 120 μl of lysozyme (10 mg/ml) was added and gently mixed using a pipet. Next, the mixture was incubated at 37°C for 40 min, centrifuged for 2 min at 16,000 x g and the supernatant was removed. Thereafter, 600 μl of nuclei lysis solution was added, gently mixed using a pipet and incubated at 80°C for 5 min. RNase solution (3 μl) was then added and incubated at 37°C for 40 min. Then, 200 μl of protein precipitation solution was added and mixed vigorously for 20 sec. The samples were then cooled on ice for 5 min and centrifuged at 16,000 x g for 3 min. The supernatant (genomic DNA) was then transferred into a new tube and 600 μl of isopropanol was added and gently mixed by inversion until thread-like strands of DNA were formed. The mixture was then centrifuged at 16,000 x g for 2 min. At this point, the supernatant was poured off. Then, 600 μl of 70% ethanol was added and the mixture was centrifuged at 16,000 x g for 2 min. Next, the supernatant was poured off and 100 μl of DNA rehydration solution was added and incubated overnight at 4°C. The DNA concentration was measured using a Nanodrop spectrophotometer (Thermo Scientific - USA).

Polymerase Chain Reaction
The detection of Firmicutes and Bacteroidetes from saliva samples was performed via polymerase chain reaction (PCR). FirmF (5’GGCGTGAGTGAAGT3’) and FirmR (5’CTACGCTCCCTTTACAC3’) primers were used to detect the Firmicutes phylum (161 bp). BactF (5’AACGCTAGCTACAGGCTTAACA3’) and BactR (5’ACGCTACTTGGCTGGTTCA3’) primers were used to detect the Bacteroidetes phylum (396 bp). PCR amplification reactions were prepared for a final volume of 20 μl and contained the following: 10 μl PCR master mix (Promega – USA), 7 μl nuclease-free deionised water, 1 μl of each forward and reverse primer (10 pmol/μl) and 1 μl of genomic DNA (25–50 ng/μl). For the detection of the Firmicutes, the reaction was started with one cycle at 95°C for 5 min for denaturation, followed by 35 cycles consisting of 45 sec of denaturation at 94°C. Annealing was performed at 60°C for 30 sec, with a 45-sec extension at 72°C and a final 7-min cycle at 72°C. For Bacteroidetes detection, the reaction was started with one cycle at 95°C for 5 min
to achieve denaturation, followed by 30 cycles consisting of denaturation for 30 sec at 94°C, annealing for 20 sec at 65°C, extension for 60 sec at 72°C and a final cycle of 5 min at 72°C. PCR products were run on a 1% (w/v) agarose gel (Amersham – USA) at 65 V for 40 min. Agarose gels were stained by ethidium bromide at a final concentration of 0.5 μg/ml for 40 min. DNA bands were visualised under UV light at 366 nm. The sizes of PCR products were assessed by a (100–1500 bp) DNA ladder (Atom Scientific - UK).

Ethics Statement
This study and its protocol for obtaining consent were approved by the Scientific Committee of the College of Sciences, University of Duhok, Kurdistan Region, Iraq (amended in September 2018). Consent was obtained from the patients recruited for this study.

Statistical Analysis
Statistical analysis was conducted using the chi-squared test. The statistical analysis was performed using Minitab 18 software. P-values <0.05 were considered significant.

Results
The salivary samples for all 155 participants were screened for the presence of Firmicutes and Bacteroidetes using PCR. Two sets of universal oligonucleotide primers were used to detect Firmicutes (FirmF and FirmR) and Bacteroidetes (BactF and BactR) by targeting 16S rRNA. DNA was successfully extracted from all saliva samples. All DNA was examined via PCR analysis. The PCR products were run and then visualised via agarose gel electrophoresis. PCR products with an expected size of ~161 bp were considered positive for Firmicutes (Figure 1).

Figure 1. 1% agarose gel analysis showing the amplicon bands from the PCR product of Firmicutes. Lanes: M, 100 bp DNA marker; 1–14, (except line 9; negative) ~161 bp fragments amplified using FirmF and FirmR primers for screened DNA samples.

Figure 2. 1% agarose gel analysis showing the amplicon bands from the PCR product for Bacteroidetes. Lanes: M, 100 bp DNA marker; 1–14, ~396 bp fragments amplified using BactF and BactR primers for screened DNA samples.

PCR fragments of ~396 bp were deemed positive for Bacteroidetes (Figure 2). The 155 participants were divided into three groups: 61 normal weight individuals (control group; BMI=18.5–24.9 kg/m²), 41 overweight individuals (BMI=25.0–29.9 kg/m²) and 53 obese individuals (BMI ≥30 kg/m²).

Overall, 98/155 (63.2%) of the participants were positive for Firmicutes and 58/155 (37.4%) were positive for Bacteroidetes. Moreover, 34/155 (21.9%) of the participants were positive for both Firmicutes and Bacteroidetes. The relative abundance of Firmicutes and Bacteroidetes substantially varied between the different BMI categories. Overall, the carriage rates of oral Firmicutes bacteria were 36, 78 and 83% in normal weight, overweight and obese individuals, respectively (Table 1). The differences in Firmicutes carriage rates among these categories were statistically significant (P<0.0001).

The percentage rates of Bacteroidetes among the normal weight, overweight, obese groups were 50.8, 31.7 and 26.4%, respectively. In general, these differences were statistically significant (P=0.0184). The average abundances of both phyla in salivary samples for all BMI categories are presented in Figure 3.

It was observed that the frequencies of oral Firmicutes in obese (n=44) and overweight individuals (n=32) were markedly different from that of normal weight individuals (n=22). The Firmicutes level in obese individuals (n=44) was higher than the level in overweight individuals (n=32). However, this difference was not statistically significant (P=0.5436 (Table 1).
Table 1. Distribution of Bacteroidetes and Firmicutes in obese, overweight and normal weight individuals.

<table>
<thead>
<tr>
<th>BMI groups</th>
<th>Firmicutes</th>
<th>Bacteroidetes</th>
<th>F/B ***</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Positive n(%)</td>
<td>Negative n(%)</td>
<td>P *</td>
</tr>
<tr>
<td>Normal (n=61)</td>
<td>22 (36)</td>
<td>39 (64)</td>
<td>0.7</td>
</tr>
<tr>
<td>Overweight (n=41)</td>
<td>32 (78)</td>
<td>9 (22)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Obese (n=53)</td>
<td>44 (83)</td>
<td>9 (17)</td>
<td>&lt;0.0001</td>
</tr>
</tbody>
</table>

* P-value of Firmicutes carriers compared to normal weight individuals.
** P-value of Bacteroidetes carriers compared to normal weight individuals.
*** Firmicutes/Bacteroidetes ratio in positive carriers.

Figure 3. Average abundance of Firmicutes and Bacteroidetes in the saliva samples of obese, overweight and normal weight individuals.

The phylum Bacteroidetes was significantly less abundant in obese individuals (n=14) in comparison to normal weight individuals (n=31) (P=0.0078). Also, the prevalence of Bacteroidetes in overweight individuals (n=13) was lower in comparison to normal weight individuals (n=31); however, this difference was not statistically significant (P=0.0560).

The prevalence of Bacteroidetes in obese individuals (26.4%) was lower than that in overweight individuals (31.7%). However, this difference was not statistically significant (P=0.5738).

In the male population, the prevalence of Firmicutes in overweight individuals was higher than in obese individuals, and both of these levels were significantly higher than those of normal weight individuals (P<0.0001 and P=0.0361, respectively). However, Bacteroidetes prevalence was significantly higher in normal weight individuals than in overweight individuals (P=0.0484), but not significantly higher than in obese individuals (P=0.3912) (Table 1).

In the female population, the Firmicutes rate in obese individuals was significantly higher than in normal weight individuals (P<0.0001). No significant difference was observed between Firmicutes prevalence in overweight and normal weight individuals (P=0.0525). However, a higher prevalence of Bacteroidetes was observed in normal weight individuals. This prevalence was significantly higher than that in obese individuals (P=0.0039) but not significantly higher than that in overweight individuals (P=0.4225) (Table 1).

Generally, the phylum Firmicutes was more abundant in individuals with higher BMI, while the phylum Bacteroidetes was less abundant in such individuals. Hence, the relative abundance of the F/B ratio was also higher with increasing BMI. The F/B ratio was 3.1 (44/14) in the obese group, 2.5 (32/13) in the overweight group and 0.7 (22/31) in the control group (Table 1 and Figure 4).

Discussion

Obesity has become a significant public health problem worldwide. Although a tremendous amount of research has focused on the causes of obesity, its exact mechanism remains to be fully elucidated.26 The interaction between genetics and the environment is the result of complex pathological adaptations by cells in the human body and represents the most...
essential factor contributing to obesity.\textsuperscript{6,27} Moreover, studies have noted that potential environmental impacts such as diet, energy expenditure, early life influences, sleep deprivation, endocrine disruptors, drugs, chronic inflammation and microbiome status contribute to a higher risk of obesity.\textsuperscript{28} The purpose of this study was to characterise the salivary Firmicutes and Bacteroidetes bacterial profiles of healthy individuals with different BMIs in Duhok, Iraq.

The present study used a molecular technique (PCR) and detected high levels of oral Firmicutes (63.2%) and Bacteroidetes (37.4%) among participants. The oral cavity is colonised by a complex microbiota, with the largest and most diverse group being bacteria—many of which cannot be successfully cultivated in the laboratory.\textsuperscript{29} Cultivation methods for the isolation and identification of oral bacteria require complex procedures for diagnosis, which can be time-consuming and expensive. Therefore, the detection of oral organisms is now based on molecular techniques, especially the PCR method.\textsuperscript{30,31}

The upper digestive tract harbours microbes and diverse ecosystems, including the teeth, gingival sulcus, tongue, cheeks, hard and soft palates and tonsils.\textsuperscript{32} The Human Oral Microbiome Database (HOMD) includes 619 taxa in 13 phyla. Among these, Firmicutes, Bacteroidetes, Proteobacteria, Actinobacteria, Spirochaetes and Fusobacteria are the six major phyla that contain 96% of the taxa.\textsuperscript{33} The phylum Firmicutes is almost entirely composed of gram-positive bacteria and includes five major classes: Bacilli, Clostridia, Mollicutes, Thermolithobacteria and Negativicutes.\textsuperscript{34,35} On the other hand, the phylum Bacteroidetes is characterised by gram-negative bacteria and includes four major classes: Bacteroidia, Cytophagia, Flavobacteria and Sphingobacteria.\textsuperscript{36}

In the present study, the general carriage rates of Firmicutes were significantly higher with an increase in BMI, whilst the rates of Bacteroidetes were significantly lower under the same condition. The association between salivary bacterial profile and obesity has been reported in many studies.\textsuperscript{13,33} Both obese males and females had significantly higher levels of Firmicutes and lower levels of Bacteroidetes when compared to normal weight individuals, which is in agreement with a previous study.\textsuperscript{8} The high proportion of Firmicutes may play a causative role in the development of obesity. There is strong evidence to suggest that the prevalence of Firmicutes can serve an essential role in the regulation of weight and body composition.\textsuperscript{13,37}

In the present study, the oral profile of the F/B ratio was gradually more abundant with increasing BMI. The F/B was 3.1 in the obese group, 2.5 in the overweight group and 0.7 in the control group. According to the literature, evidence from several human models with participants from different countries emphasise that alterations to gut microbiota communities—particularly increases in the F/B ratio—have been observed.\textsuperscript{38-40} It is known that the presence of specific microbes in the gut (e.g., Firmicutes) can promote the absorption of monosaccharides and serve a role in the development of obesity.\textsuperscript{41,42} Similar to our findings, various studies reported consistent data regarding the F/B ratio. For example, one study noted significant differences between the two phyla in the oral cavity but not in the gut. This suggests that the oral microbiota is established with potential signatures of obesity that occur earlier than in the gut microbiota.\textsuperscript{43}

However, several studies have produced contradictory results. For example, some investigations have failed to find significant alterations to the F/B ratio between normal weight and obese phenotypes.\textsuperscript{11,12,44} Piombino et al. (2014) observed a higher proportion of Bacteroidetes in the saliva of obese compared to normal weight individuals; however, this result was not statistically significant.\textsuperscript{8} Also, Schwirtz et al. (2010) observed the predominance of Bacteroidetes in the guts of both overweight and obese individuals when compared to those of normal weight.\textsuperscript{45}
The majority of the Firmicutes phylum includes two main groups, known as Clostridium cluster XIVa and Clostridium cluster IV. Members in Clostridium cluster XIV are the primary fermenters of carbohydrates within the gut and produce short-chain fatty acids (SCFAs) as the principal end product of this fermentation. Moreover, a decrease in Clostridium cluster XIVa can result in the reduction of intestinal fermentation and fewer SCFAs or food for the intestinal epithelial cells. One possible mechanism related to how the microbiome participates in obesity is SCFAs providing additional calories when they are oxidised by the host, which leads to fat gain. Also, the binding and activation of G protein-coupled receptors with the released SCFA result in the secretion of hormone peptide YY (PYY). This hormone reduces intestinal transit time, thereby increasing the time required for nutrient absorption from the intestinal lumen.

Several studies have shown an insulin resistance state with increased levels of plasma lipopolysaccharide (LPS)-binding protein in obese subjects. Despite LPS secretion, the intestinal microbiota also produce many molecules that promote inflammation (e.g., peptidoglycans and flagellins), which activate inflammatory pathways and result in obesity and insulin resistance. Fat is considered a reservoir for inflammatory cytokines, and it has been suggested that obesity likely affects periodontal disease through this pathway.

Furthermore, studies have shown that periodontal bacteria could induce the generation of inflammatory cytokines such as tumour necrosis factor α (TNFα), which alters the metabolism of energy to the synthesis of lipid and can thus contribute to obesity. Additionally, it was shown that the decrease in circulation C-reactive protein CRP is directly associated with the amount of weight loss. In addition to a reduction in plasma, inflammatory cytokine levels have also been directly observed after weight loss in obese phenotypes.

It was hypothesised that oral bacteria could serve a role in obesity via three mechanisms. First, they redirect energy metabolism by increasing insulin resistance in response to increasing TNF. Secondly, bacteria increase metabolic efficiency (consuming even small amounts of calories), which causes the body to gain weight without changes in exercise and diet. Third, they can increase the appetite of the host; however, there is no research to support this theory.

Although oral hygiene is the primary cause of oral microbial dysbiosis, antibiotic treatments can also be considered an essential factor affecting microbial composition.

Thus, any disturbance to the microbial ecosystem can change the F/B ratio, which can lead to an increase in the proportion of Firmicutes and thus a higher absorption of fats, which ultimately increases both the weight and fat proportion of the host. The reasons for the connection between obesity and oral bacteria are undoubtedly complex and diverse. These relationships can be indirect since they are related to diet, drugs, smoking or perhaps the return to different physiological natures of a host. This is supported by evidence of microbiota differing between obese and normal weight individuals.

A potential therapy for controlling weight gain in both obese and overweight individuals via the selective modulation of microbiota using probiotics and/or prebiotics has emerged. This could be an alternative step in standard treatments such as bariatric surgery and non-surgical multicomponent approaches, which are known to have side effects and high costs.

One limitation of our study is that it used PCR based analysis. Since PCR is a highly sensitive method, any form of DNA contamination can lead to the detection of unclassified microbes. Additionally, more advanced methods (e.g., 16S metagenome sequencing) could provide a more robust analysis.

Conclusions
This study provided evidence of the saliva microbiota being positively associated with obesity. Moreover, this is the first study to show that obesity is associated with oral Firmicutes and Bacteroidetes composition in the Iraqi population. Our results demonstrate that Firmicutes were more abundant in obese individuals, whilst the Bacteroidetes were dominant in the normal weight group. Moreover, individuals with higher BMI were more susceptible to the oral colonisation...
and retention of Firmicutes, which could be considered a factor linked to the development of obesity. Thus, obese individuals may be treated via the alteration of microbial communities in their oral cavity rather than by standard treatments such as bariatric surgery and the use of drugs that are costly and have side effects. However, further studies with larger sample sizes that include individuals with different demographic statuses may be required to clarify the exact relationship between oral bacteria and obesity. If the human oral microbiome is proven to serve a role in obesity, the next step could involve new and promising therapeutic approaches that provide a new target for improving the physical health of humans.

References


Awareness, knowledge, attitudes and practices on the management of diabetes mellitus patients with periodontitis amongst Malaysian primary care practitioners

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Abstract

**Introduction:** The bi-directional relationship between periodontitis (PD) and diabetes mellitus (DM) has been confirmed. Medical practitioners (MPs) serve an important role in relaying this information to patients. This study aimed to investigate the awareness, knowledge, attitudes and practices (KAP) in the management of DM patients with PD in primary care clinics under the Ministry of Health (MOH) of Malaysia.

**Materials and Methods:** A self-administered questionnaire on KAP in the management of DM patients with PD was posted to 725 medical officers (MOs) and family medicine specialists (FMSs) in MOH clinics in Kedah, Terengganu, Johor and Negeri Sembilan. Collected data were tabulated and analysed using descriptive and regression analyses (simple and multiple). Statistical significance was defined as p < 0.05.

**Results:** A total of 549 MPs responded. The majority of MPs were MOs (92.6%) and female (75.8%). FMSs had a greater awareness of PD when compared to MOs (p = 0.002). All MPs had good knowledge, except for the incorrect notion that excessive sugar causes PD (94.3%). Overall, FMSs had better knowledge when compared to MOs (p=0.026). The majority of MPs agreed that they should update their knowledge on the association between systemic disease and PD (89.6%) and claimed that it was not their responsibility to examine DM patients for PD (83.1%). Most MPs did not enquire or examine for PD in their DM patients. More FMSs (67.5%) referred patients to dentists compared to MOs (31.6%).

**Conclusion:** Most MPs have sufficient knowledge on PD, but a negative attitude in the management of PD in DM patients. The reasons for not referring included workload and patients refusing referral.

Introduction

Periodontitis (PD) is a chronic inflammatory disease affecting tooth-supporting structures. It causes the loss of periodontal attachment and progressive alveolar bone loss, which results in tooth loss. Severe PD is the sixth most prevalent disease worldwide, with a prevalence of 11.2% (approximately 743 million people affected).

The bi-directional relationship between PD and DM has been widely accepted. Poorly controlled DM patients may have a higher risk of developing severe PD when compared to non-DM controls. Conversely, PD patients with DM exhibit poorer glycaemic control and a higher presence of diabetes-related complications. Following periodontal therapy, reductions in glycated haemoglobin (HbA1c; ranging from 0.27 to 0.48%) have been reported at 3 months post-therapy, which are equivalent to those achieved by adding a second medication to the diabetes pharmacological regime.

Most DM patients in Malaysia are managed by medical practitioners (MPs) in government-run primary health clinics based on the Malaysian Clinical Practice Guidelines (CPGs) for the management of DM patients. MPs must have knowledge and awareness of the dynamics of these two important diseases
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Studies have reported that awareness could be associated with better practices.7,8 Attitudes are also expected to serve an important role in the outcomes of clinical care in the management of DM patients with PD.5,10 A qualitative study in the United Kingdom concluded that the knowledge of DM nurses, dental professionals and medical doctors were limited regarding the link between both diseases.11 Similar findings were also reported in India and Jordan.5,12,13 In contrast, family medicine specialists (FMSs) in Hong Kong reported that the majority (92%) of them were aware of the effects of poor glycaemic control on PD; however, only 76% were aware of the reverse effect that PD has on DM (p = 0.02). In terms of their clinical practice, only 5.7% routinely asked patients about their dental history, whilst 7.1% often examined their patients’ mouths and 12.1% recommended that their patients visit a dentist. It was shown that the more knowledgeable the MPs were, the more likely they were to make dental referrals.7

It is important to understand the barriers to identify opportunities that may help to improve the quality of diabetes care, such as the improvement of metabolic control and diabetes self-management.14 It has previously been postulated that it is not the MP’s responsibility to perform oral examinations.9 Moreover, MPs may have received limited training in oral health knowledge/education in medical school.10

In 2017, Salleh et al. assessed the perceptions and practices of Malaysian medical personnel—including medical officers (MOs) and FMSs—in referring DM patients to receive dental care.15 However, they did not assess the knowledge and awareness of these MPs in the DM management of patients with PD. Therefore, the present study aimed to assess the awareness, knowledge, attitudes and practices (KAP) of Malaysian MPs in the DM management of patients with PD and identify the associated barriers.

Methods
This was a cross-sectional study conducted on MPs in the Ministry of Health (MOH) of Malaysia. Ethical clearance for this study was granted by the Medical Ethics Committee, Faculty of Dentistry, University of Malaya (reference number: DF RD1718/0059(P)) and the Medical Research and Ethics Committee, Ministry of Health, Malaysia (NMRR-17-2830-38175).

A self-administered questionnaire survey was distributed to MOs and FMSs practising in the four states (Kedah, Terengganu, Johor and Negeri Sembilan) with the highest prevalence of DM in Malaysia based on the National Health and Morbidity Survey 2015.16 The convenience sampling method was used in this study and the study population comprised all MPs who were involved in diabetic patient management in all primary care clinics with resident FMSs in the four respective states. MPs who practised in clinics without resident FMSs were excluded. Sample size estimation was performed based on the previous literature8,17. It was found that 70% of the medical doctors reportedly knew about the relationship between diabetes and periodontal disease. Thus, the expected prevalence for the calculation was 70%. The acceptable sample size was 386, including a 20% dropout rate.

The questions in the questionnaire were adapted from several studies for each domain and measured7,8,15,18 as follows:

1) Demographics - Seven questions related to the respondent’s background.

2) Social and oral health habits - Four questions on the respondent’s social and oral health habits as well as their perception of their oral health. Responses are scored on a five-point scale (very good, good, fair, poor and very poor).

3) Awareness of the PD-DM bi-directional relationship - Three questions covering the association of uncontrolled diabetes with PD and interventions/treatments that may control diabetic status. For this domain, there were three possible responses for each item: ‘yes’, ‘no’ and ‘do not know’. Each correct answer to a question was given a score of 1, whilst an incorrect or ‘do not know’ answer was given a score of 0. The overall score was the sum of the scores for the three questions and ranged from 0 to 3, with higher scores indicating better awareness. For the assessment of awareness level, the respondents were divided into good and poor awareness groups based on their mean awareness scores.
4) Knowledge of PD - Eight questions were related to knowledge of PD, knowledge of causative factors/modifying factors of PD and knowledge of the signs and symptoms of PD. The response options for each item were ‘yes’, ‘no’ and ‘do not know’. Each correct answer to a question was given a score of 1, whilst an incorrect or ‘do not know’ answer was given a score of 0. The overall score was the sum of the scores for the eight questions and ranged from 0 to 8, with higher scores indicating better knowledge. The respondent’s level of knowledge was also categorised into good or poor based on their mean knowledge score (Table 2).

5) Attitudes towards the management of DM patients with PD - Five questions were related to the respondent’s attitudes towards the management of diabetic patients with PD and covered attitudes towards updating knowledge on diabetes mellitus and PD, identifying PD, educating diabetic patients about PD and referring diabetic patients to dental clinics. The attitude questions were scored on a 5-point Likert scale: 1 point for ‘strongly disagree’, 2 for ‘disagree’, 3 for ‘neither agree nor disagree’, 4 for ‘agree’ and 5 for ‘strongly agree’. Depending on the statements, each response was then categorised into having a positive attitude (score of 1) or a negative attitude (score of 0). The overall attitude score was the sum of the scores for the five questions and ranged from 0 to 5, with higher scores indicating a better attitude. The respondents’ attitudes towards their management of diabetic patients with periodontal disease were categorised into positive or negative based on their mean attitude scores.

6) Practice behaviour in the management of DM patients with PD - Three questions related to practices covered enquiries about patients’ oral health, the examination of patients’ oral health and the referral of diabetic patients to a dental clinic. For this domain, there were three possible responses for each item: ‘yes’, ‘no’ and ‘do not know’. Positive practices were given a score of 1, whilst negative practices or ‘no’ answers were given a score of 0. The overall score was the sum of the scores for the three questions and ranged from 0 to 3, with higher scores indicating better practices. The respondents’ practices in their management of diabetic patients with periodontal disease were divided into good and poor practices based on their mean practice scores (Table 2).

7) Barriers to the management of DM patients with periodontal disease - Six questions were related to the barriers experienced by MPs in their management of diabetic patients with periodontal disease. These barriers included patient factors, healthcare professional factors and health service factors. The respondents were asked to identify barriers in their management of DM with periodontal disease.

Content validation was performed with one dental public health specialist and three periodontists. Pre-testing of the questionnaire was then performed with 10 FMSs and MOs at Klinik Kesihatan Sungai Buloh for face validation. These FMSs and MOs were not involved with the final survey. A total of 725 questionnaires were distributed from September to December 2018. The distribution and collection of survey forms were performed through state representatives.

**Data Analysis**

Data were described using the means and standard deviations for continuous variables and the frequency distributions for categorical variables. In this study, the dependent variables were the level of awareness, knowledge, attitudes and practices. Simple and multiple logistic regression analyses were performed to investigate potential relationships between demographic variables (i.e., age, gender, ethnicity, profession and years of service), smoking status and perceived oral health status with the level of awareness, knowledge, attitude and practice scores. In the logistic regression analysis, a dummy variable was created for categorical independent variables with more than two categories and identified reference options. Adjusted p-values were considered significant at the 0.05 level. All analyses were performed using Statistical Package for Social Science (SPSS), version 20.

**Results**

Out of the 725 questionnaires distributed, 549 (75%) were returned. Three questionnaires were excluded due to incomplete data. A total of 506 MOs (92.7%) and 40 FMSs (7.3%)
responded. The mean age of MPs was 33.31 (SD = 5.9) years, with a range of 25–56 years. The majority of MPs were female (75.8%) and Malay (80.6%).

Table 1 presents the distribution of MPs’ responses regarding their awareness of the relationship between DM and PD. Most MPs were aware of the bi-directional relationship between DM and PD and that uncontrolled DM patients had a higher risk of developing PD. When compared to MOs, FMSs had better awareness of the effect of periodontal treatment on DM patients’ glycaemic control.

### Table 1. Percentage distribution of the awareness status of MPs regarding the relationship between DM and PD.

<table>
<thead>
<tr>
<th>Awareness statement</th>
<th>Medical officers (N=506) n(%)</th>
<th>Family medicine specialists (N=40) n(%)</th>
<th>Total (N=546) n(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q1: There is a bi-directional relationship between DM and periodontal disease.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>403(79.6)</td>
<td>37(92.5)</td>
<td>440(80.6)</td>
</tr>
<tr>
<td>No</td>
<td>103(20.4)</td>
<td>3(7.5)</td>
<td>106(19.4)</td>
</tr>
<tr>
<td>Q2: Uncontrolled diabetic patients have a higher risk of developing periodontal disease.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>475(93.9)</td>
<td>40(100)</td>
<td>515(94.7)</td>
</tr>
<tr>
<td>No</td>
<td>31(1.8)</td>
<td>0</td>
<td>31(5.6)</td>
</tr>
<tr>
<td>Q3: Periodontal treatment can improve the glycaemic control of a diabetic patient.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>203(40.1)</td>
<td>25(62.5)</td>
<td>228(41.8)</td>
</tr>
<tr>
<td>No</td>
<td>303(60.1)</td>
<td>15(37.5)</td>
<td>318(58.2)</td>
</tr>
</tbody>
</table>

The distributions and mean KAP scores of the MPs are presented in Table 2.

Table 2. Status and mean scores of MPs’ awareness, knowledge, attitudes and practices related to the management of DM patients with PD.

<table>
<thead>
<tr>
<th>Domain</th>
<th>Medical officers (N=506)</th>
<th>Family medicine specialists (N=40)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Awareness</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Status</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Good [n(%)]</td>
<td>413(81.6)</td>
<td>39(98.9)</td>
<td>*0.01</td>
</tr>
<tr>
<td>Poor [n(%)]</td>
<td>93(18.4)</td>
<td>1(2.5)</td>
<td></td>
</tr>
<tr>
<td>Total score [Mean (SD)]</td>
<td>2.14(0.82)</td>
<td>2.55(0.5)</td>
<td>*0.02</td>
</tr>
<tr>
<td><strong>Knowledge</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Status</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Good [n(%)]</td>
<td>492(97.2)</td>
<td>40(100)</td>
<td>0.29</td>
</tr>
<tr>
<td>Poor [n(%)]</td>
<td>14(2.8)</td>
<td>0(0)</td>
<td></td>
</tr>
<tr>
<td>Total score [Mean(SD)]</td>
<td>2.14(0.82)</td>
<td>2.55(0.5)</td>
<td>0.28</td>
</tr>
<tr>
<td><strong>Attitude</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Status</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Positive [n(%)]</td>
<td>157(31)</td>
<td>15(37.5)</td>
<td>0.39</td>
</tr>
<tr>
<td>Negative [n(%)]</td>
<td>349(69)</td>
<td>25(62.5)</td>
<td></td>
</tr>
<tr>
<td>Total score [Mean(SD)]</td>
<td>2.26(0.86)</td>
<td>2.43(0.84)</td>
<td>0.8</td>
</tr>
<tr>
<td><strong>Practice</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Status</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Positive [n(%)]</td>
<td>121(23.9)</td>
<td>19(47.5)</td>
<td>*0.01</td>
</tr>
<tr>
<td>Negative [n(%)]</td>
<td>385(76.1)</td>
<td>21(52.5)</td>
<td></td>
</tr>
<tr>
<td>Total score [Mean(SD)]</td>
<td>0.81(1.06)</td>
<td>1.45(1.20)</td>
<td>*0.00</td>
</tr>
</tbody>
</table>

a: Pearson’s chi-squared test, *: Significant difference observed between groups at p<0.05.
Table 3 presents the distribution of MPs’ responses regarding their knowledge of PD. Most of the MPs had good knowledge of PD, except for knowledge on whether excessive sugar intake could cause PD since most of the MPs either did not know or chose the incorrect answer. Of the 546 MPs, only 3.1% provided the correct response to this question (3% of the MOs and 5% of the FMSs). For the assessment of MPs’ knowledge, MPs were divided into good and poor knowledge groups (Table 2). Overall, 97.2% of MOs and 100% of FMSs exhibited good knowledge, with mean scores of 6.63 (SD = 0.78) and 6.8 (SD = 0.52) respectively. However, there was no significant difference between the good and poor knowledge score groups for MOs and FMSs ($p = 0.29$). There was also no significant difference in the total knowledge score between FMSs and MOs ($p = 0.28$).

Table 3. Percentage distribution of MPs’ knowledge on PD.

<table>
<thead>
<tr>
<th>Knowledge statement</th>
<th>Medical officers (N=506) n(%)</th>
<th>Family medicine specialists (N=40) n(%)</th>
<th>Total (N=546) n(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q1: Dental plaque can cause periodontal disease.</td>
<td>480(94.8) 26(5.2)</td>
<td>38(95) 2(5)</td>
<td>518(94.9) 28(5.1)</td>
</tr>
<tr>
<td>Q2: Gingivitis appears clinically as inflammation of the gingiva (gums).</td>
<td>503(99.4) 3(0.6)</td>
<td>40(100) 0</td>
<td>543(99.5) 3(0.6)</td>
</tr>
<tr>
<td>Q3: Smoking is a modifying risk factor for periodontitis.</td>
<td>493(97.4) 13(2.6)</td>
<td>40(100) 0</td>
<td>533(97.6) 13(0.4)</td>
</tr>
<tr>
<td>Q4: Excessive sugar intake can cause periodontitis.</td>
<td>477(94.3) 29(5.7)</td>
<td>38(95) 2(5)</td>
<td>515(94.3) 31(5.7)</td>
</tr>
<tr>
<td>Q5: Bleeding from the gingiva (gums) can be a sign of periodontitis.</td>
<td>462(91.3) 44(8.7)</td>
<td>40(100) 0</td>
<td>502(91.9) 44(8.1)</td>
</tr>
<tr>
<td>Q6: Periodontitis can cause teeth to become mobile.</td>
<td>438(86.6) 68(13.4)</td>
<td>39(97.5) 1(2.5)</td>
<td>477(87.4) 69(12.6)</td>
</tr>
<tr>
<td>Q7: Gingival/gum swelling may be a symptom of periodontitis.</td>
<td>490(96.8) 16(3.2)</td>
<td>39(97.5) 1(2.5)</td>
<td>529(96.9) 17(3.1)</td>
</tr>
<tr>
<td>Q8: Halitosis (bad breath) may be a symptom of periodontitis.</td>
<td>476(94.1) 30(5.9)</td>
<td>37(92.5) 3(7.5)</td>
<td>513(94) 33(6)</td>
</tr>
</tbody>
</table>

Table 4 presents the distribution of MPs’ responses regarding their attitudes in the management of DM patients with PD. The majority of the MPs agreed to the statements ‘overall health cannot affect periodontal health’ (81.4%), ‘it is not their responsibility to look into a patient’s mouth to detect periodontal problems’, ‘they should update their knowledge on the association between systemic disease and PD’ and ‘they should help to educate DM patients on their increased risk of getting PD’. Regarding the need for all DM patients to receive a dental referral, half of the MPs agreed with the statement that there was no need for them to refer all DM patients to a dentist.
Overall, 31% of MOs and 37.5% of FMSs exhibited positive attitudes, with mean scores of 2.26 (SD = 0.85) and 2.43 (SD = 0.84), respectively (p > 0.05) (Table 2). No significant differences were observed in the attitude scores between FMSs and MOs.

**Table 4. Distribution of MPs’ attitudes in their management of diabetic patients.**

<table>
<thead>
<tr>
<th>Attitude statement</th>
<th>Medical officers (N=506) n(%)</th>
<th>Family medicine specialists (N=40) n(%)</th>
<th>Total (N=546) n(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q1: I don’t feel that overall health can affect periodontal health.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fully disagree</td>
<td>22(4.4)</td>
<td>1(2.5)</td>
<td>23(4.2)</td>
</tr>
<tr>
<td>Somewhat disagree</td>
<td>57(11.3)</td>
<td>2(5)</td>
<td>59(10.8)</td>
</tr>
<tr>
<td>I do not know</td>
<td>20(4)</td>
<td>0(0)</td>
<td>20(3.7)</td>
</tr>
<tr>
<td>Somewhat agree</td>
<td>175(34.7)</td>
<td>10(25)</td>
<td>185(34)</td>
</tr>
<tr>
<td>Fully agree</td>
<td>232(45.8)</td>
<td>27(67.5)</td>
<td>259(47.4)</td>
</tr>
<tr>
<td>Q2: It is not my responsibility to look into a patient’s mouth to detect a periodontal problem.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fully disagree</td>
<td>12(2.4)</td>
<td>1(2.5)</td>
<td>13(2.4)</td>
</tr>
<tr>
<td>Somewhat disagree</td>
<td>72(14.2)</td>
<td>8(20)</td>
<td>80(14.7)</td>
</tr>
<tr>
<td>I do not know</td>
<td>52(10.3)</td>
<td>1(2.5)</td>
<td>53(9.7)</td>
</tr>
<tr>
<td>Somewhat agree</td>
<td>174(34.4)</td>
<td>11(27.5)</td>
<td>185(34)</td>
</tr>
<tr>
<td>Fully agree</td>
<td>196(38.7)</td>
<td>19(47.5)</td>
<td>215(39.4)</td>
</tr>
<tr>
<td>Q3: I should update my knowledge on the association between systemic disease and periodontitis.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fully disagree</td>
<td>24(4.7)</td>
<td>1(2.5)</td>
<td>25(4.9)</td>
</tr>
<tr>
<td>Somewhat disagree</td>
<td>12(2.4)</td>
<td>2(5)</td>
<td>14(2.6)</td>
</tr>
<tr>
<td>I do not know</td>
<td>12(2.4)</td>
<td>1(2.5)</td>
<td>13(2.3)</td>
</tr>
<tr>
<td>Somewhat agree</td>
<td>176(34.8)</td>
<td>14(35)</td>
<td>190(34.8)</td>
</tr>
<tr>
<td>Fully agree</td>
<td>277(54.7)</td>
<td>22(55)</td>
<td>299(54.8)</td>
</tr>
<tr>
<td>Q4: I should help to educate diabetic patients on their risk of getting periodontitis.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fully disagree</td>
<td>21(4.2)</td>
<td>1(2.5)</td>
<td>22(4)</td>
</tr>
<tr>
<td>Somewhat disagree</td>
<td>15(3)</td>
<td>1(2.5)</td>
<td>16(2.9)</td>
</tr>
<tr>
<td>I do not know</td>
<td>25(4.9)</td>
<td>0(0)</td>
<td>25(4.9)</td>
</tr>
<tr>
<td>Somewhat agree</td>
<td>177(35)</td>
<td>13(32.5)</td>
<td>190(34.8)</td>
</tr>
<tr>
<td>Fully agree</td>
<td>268(53)</td>
<td>25(62.5)</td>
<td>293(53.7)</td>
</tr>
<tr>
<td>Q5: There is no need for dental referrals for all diabetic patients.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fully disagree</td>
<td>5(3)</td>
<td>4(10)</td>
<td>9(1.6)</td>
</tr>
<tr>
<td>Somewhat disagree</td>
<td>67(13.2)</td>
<td>7(9.5)</td>
<td>74(13.6)</td>
</tr>
<tr>
<td>I do not know</td>
<td>124(24.5)</td>
<td>4(10)</td>
<td>128(23.4)</td>
</tr>
<tr>
<td>Somewhat agree</td>
<td>148(29.2)</td>
<td>9(22.5)</td>
<td>157(27.1)</td>
</tr>
<tr>
<td>Fully agree</td>
<td>152(30)</td>
<td>16(40)</td>
<td>168(30.8)</td>
</tr>
</tbody>
</table>

Regarding the MPs’ practices in the management of DM patients, the majority of them did not ask their patients whether they had any symptoms of PD. In comparison, more FMSs examined and referred their patients for PD.

Overall, 76.1% of MOs with poor practices were represented by a mean practice score of 0.81 (SD = 1.06) (Table 2). There were significantly more ‘poor practice’ compared to ‘good practice’ scores in both groups (p = 0.01). Moreover, mean total practice scores were significantly higher among the FMSs when compared to the MOs (p = 0.00).
Table 5. Percentage distribution of MPs’ knowledge on PD.

<table>
<thead>
<tr>
<th>Practices questions</th>
<th>Medical officers (N=506) n(%)</th>
<th>Family medicine specialists (N=40) n(%)</th>
<th>Total (N=546) n(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Q1: Do you ask your patients whether they have any symptoms of periodontitis?</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>145(28.7)</td>
<td>20(50)</td>
<td>165(30.2)</td>
</tr>
<tr>
<td>No</td>
<td>361(71.3)</td>
<td>20(50)</td>
<td>381(69.8)</td>
</tr>
<tr>
<td><strong>Q2: Do you examine your patients for signs of periodontitis?</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>104(20.6)</td>
<td>15(37.5)</td>
<td>119(21.8)</td>
</tr>
<tr>
<td>No</td>
<td>402(79.4)</td>
<td>25(62.5)</td>
<td>427(78.2)</td>
</tr>
<tr>
<td><strong>Q3: Do you refer your diabetic patients to a dentist?</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>160(31.6)</td>
<td>27(67.5)</td>
<td>187(34.2)</td>
</tr>
<tr>
<td>No</td>
<td>346(68.4)</td>
<td>13(32.5)</td>
<td>359(65.8)</td>
</tr>
</tbody>
</table>

Among all MPs, the greatest barrier to referral was workload, which was faced by more MOs than FMSs. The next barrier faced was patients refusing to be referred to a dentist (45.4%), which was similarly noted by both MOs (45.1%) and FMSs (50%). Additional barriers were less frequently experienced by the MPs and included ‘time consuming to write a referral letter to the dentist’ (26.6%), ‘oral healthcare is not part of diabetes management in the CPG - Management of DM 2015’ (15.8%), ‘dental clinic is not in the same premises as the health clinic’ (7.5%) and ‘complex referral system’ (6.8%).

Figure 1. Barriers faced during the management of diabetic patients.

Apart from the barriers listed in Figure 1, the MPs listed additional perceived barriers. The most commonly noted barriers were that referral was only done when the patient requested it, there was no guideline or standard of practice (SOP) from dental to refer DM patients, and the MPs lacked knowledge and awareness.
Table 6. Relationship between level of awareness, knowledge, attitude and practice scores and demographic characteristics.

<table>
<thead>
<tr>
<th>Domain and variables</th>
<th>Simple logistic regression</th>
<th>Multiple logistic regression</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Crude OR (95% CI)</td>
<td>p-value</td>
</tr>
<tr>
<td><strong>Awareness</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age (years old)</td>
<td>4.8 (0)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male*</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>0.52 (0.32,0.84)</td>
<td>0.007</td>
</tr>
<tr>
<td>Ethnicity</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Malay*</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Chinese</td>
<td>1.53 (0.70,3.34)</td>
<td>0.702</td>
</tr>
<tr>
<td>Indian</td>
<td>1.09 (0.13,5.90)</td>
<td>0.13</td>
</tr>
<tr>
<td>Profession</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medical Officers*</td>
<td>0.11 (0.02,0.84)</td>
<td>0.33</td>
</tr>
<tr>
<td>FM Specialist</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Years of service</td>
<td>4.8 (0)</td>
<td>*&lt;0.001</td>
</tr>
<tr>
<td>Smoking status</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Smoker*</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Non-smoker</td>
<td>0.48 (0.12,1.89)</td>
<td>0.290</td>
</tr>
<tr>
<td>Perceived OH status</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Poor*</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Very Good</td>
<td>5.00 (0.83,30.07)</td>
<td>0.081</td>
</tr>
<tr>
<td>Good</td>
<td>2.42 (0.60,9.73)</td>
<td>0.214</td>
</tr>
<tr>
<td>Fair</td>
<td>1.59 (0.39,6.40)</td>
<td>0.512</td>
</tr>
<tr>
<td>Knowledge</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age (years old)</td>
<td>0.95 (0.86,1.05)</td>
<td>0.334</td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male*</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>2.68 (0.48,14.94)</td>
<td>0.263</td>
</tr>
<tr>
<td>Ethnicity</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Malay*</td>
<td>0.25 (0.07,6.05)</td>
<td>0.076</td>
</tr>
<tr>
<td>Chinese</td>
<td>0.35 (0.08,1.05)</td>
<td>0.952</td>
</tr>
<tr>
<td>Indian</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Profession</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medical Officers*</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>FM Specialist</td>
<td>0.00</td>
<td>0.999</td>
</tr>
<tr>
<td>Years of service</td>
<td>1.07 (0.94,1.22)</td>
<td>0.311</td>
</tr>
<tr>
<td>Smoking status</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Smoker*</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Non-smoker</td>
<td>0.23 (0.02,1.91)</td>
<td>0.171</td>
</tr>
<tr>
<td>Perceived OH status</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Poor*</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Very Good</td>
<td>10.68 (2.73,41.75)</td>
<td>0.45</td>
</tr>
<tr>
<td>Good</td>
<td>6.27 (1.72,22.85)</td>
<td>0.33</td>
</tr>
<tr>
<td>Fair</td>
<td>2.42 (0.60,9.73)</td>
<td>0.23</td>
</tr>
<tr>
<td>Attitude</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age (years old)</td>
<td>1.00 (0.94,1.08)</td>
<td>0.98</td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male*</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>1.05 (0.68,1.62)</td>
<td>0.83</td>
</tr>
<tr>
<td>Ethnicity</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Malay*</td>
<td>0.64 (0.28,1.45)</td>
<td>0.46</td>
</tr>
<tr>
<td>Chinese</td>
<td>1.24 (0.71,2.18)</td>
<td>0.28</td>
</tr>
<tr>
<td>Indian</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Profession</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medical Officers*</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>FM Specialist</td>
<td>1.17 (0.48,2.83)</td>
<td>0.73</td>
</tr>
<tr>
<td>Years of service</td>
<td>1.00 (0.69,1.47)</td>
<td>0.98</td>
</tr>
<tr>
<td>Smoking status</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Smoker*</td>
<td>0.92 (0.23,3.74)</td>
<td>0.90</td>
</tr>
<tr>
<td>Non-smoker</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Perceived OH status</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Poor*</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Very Good</td>
<td>0.85 (0.18,3.98)</td>
<td>0.84</td>
</tr>
<tr>
<td>Good</td>
<td>1.12 (0.28,4.47)</td>
<td>0.87</td>
</tr>
<tr>
<td>Fair</td>
<td>0.95 (0.24,3.83)</td>
<td>0.94</td>
</tr>
</tbody>
</table>
Table 6 presents the relationship between the level of awareness, KAP score and demographic characteristics. Simple logistic regression provided preliminary results on potential associated factors (p-value <0.25). Regarding awareness level, five variables (age, gender, ethnicity, years of service and perceived oral health (OH) status) were found to be potentially significant. However, only gender and perceived OH status was found to be significant following multiple regression analysis. The odds of having high awareness were higher in female respondents (adjusted odds ratio (aOR) = 0.53, 95% CI = 0.32–0.86) and in respondents with perceived good OH status (aOR = 1.58, 95% CI = 1.09–2.28).

Regarding knowledge level, three variables (ethnicity, smoking status and perceived OH status) were found to be potentially significant. Based on the multiple regression analysis, only ethnicity was found to be significant (aOR = 0.79, 95% CI = 0.61–1.02). No factors were found to be significant for attitude level. When considering the relationship between referral patterns and respondent characteristics in the present study, a significant relationship was observed between the MPs ethnicity (aOR = 0.79, 95% CI = 0.61–1.02) and perceived oral health status (aOR = 1.71, 95% CI = 1.25–2.36) with patient referral.

**Discussion**

Our findings demonstrated good awareness status (80.6%) among MPs on the bi-directional relationship of DM and PD. Studies conducted in New York and Hong Kong involving either trainee specialists or FMSs reported higher levels of awareness (97 and 92.1%, respectively) that were not associated with age, years of experience, training status, demography or oral health behaviour. The findings from both studies are comparable to those of the FMS group in the present study, where 92.5% were aware of this relationship. The favourable results for awareness among FMSs may be due to the increased knowledge and clinical experience they possess in managing DM patients.

In the present study, the majority of MPs were able to provide satisfactory responses to questions related to PD knowledge. This may be because these MPs were updated in their knowledge regarding PD, which may have also been covered during their medical training or professional short courses conducted by the MOH, Malaysia. Most MPs had good knowledge of the aetiology, symptoms and risk factors of PD. Similar findings were also reported by a study in Turkey, where 87% of the medical doctors interviewed had knowledge about the symptoms of PD, whilst 59% of them knew that the primary clinical symptom of PD was bleeding of the gums.

In our study, only 3.1% knew that excessive sugar intake was not an aetiology for PD. This finding was comparable to a study comprising...
obstetricians in North Carolina, who provided answers such as bacteria (94%) and excess dietary sugar (80%) as an aetiology of PD.21 These findings suggest that MPs may have a vague understanding of the pathogenesis of PD, which may be attributed to limited exposure to oral health during medical training. Ahmad et al. reported that medical schools in Australia and Malaysia did not offer specific learning modules on oral health but instead offered oral health education as an integrated component of the medical curriculum in the preclinical and clinical years.22

Regarding the attitudes of MPs, only 31.4% exhibited positive attitudes towards PD in the management of DM. The higher negative attitude scores in this study were shown to disagree with the good knowledge scores on PD. This is in contrast to the findings of Quijano et al., which noted a positive correlation between self-rated knowledge and total attitude score.10 Overall, 89.6% of the MPs had a positive attitude when asked about the importance of their management of DM patients with PD. These positive attitudes were mostly attributed to the good knowledge and awareness of the relationship between both diseases. These findings were compared to the findings from a study in North Carolina, in which 88% of respondents agreed that physicians should be taught about PD and trained to screen patients with PD.9

Regarding the practices of the MPs, most were found to have ‘poor practice’ scores. However, when comparing between the groups, the FMSs exhibited significantly higher ‘good practice’ scores than the MOs. Although 97.4% of the MPs had good knowledge scores, only 30.2% asked their patients about symptoms of PD and only 34.2% referred their DM patients to the dentist. FMSs enquired (50%) and referred (67.5%) more than MOs (28.7 and 31%, respectively). However, the MPs in this study had a higher level of enquiry for their patients when compared to the findings of Quijano et al., which noted that only 18% of American internal medical trainees asked their patients about whether they were diagnosed with PD and only 24% screened their patients for the disease.10 Similar to our findings, another study of health care workers (HCWs) in Malaysia also reported a low referral pattern for DM patients to dentists (26%).15 This was despite the fact that the majority of their respondents agreed that the referral of DM patients for routine dental check-ups was necessary. In the present study, one reason for the poor referral rate to dentists could be the poor attitudes among MPs regarding PD management for their DM patients.

Despite MPs’ good awareness and knowledge status in the present study, lower patient recommendation and referral patterns were observed. This phenomenon was also observed in a few other studies from different parts of the world.7,8,10,20 To improve and promote oral health care in the population, it is vital to investigate, identify and address the key barriers that prevent access to dental care. For example, an Iranian study on hand hygiene found poor hand hygiene practices among the studied residents despite having acceptable knowledge of proper hand hygiene. The main reasons given by the residents were time constraints and heavy workload.23 In the current study, MPs' knowledge and awareness status was observed to be good but did not translate into practice.

Our findings suggest that Malays and MPs who perceived good OH were more likely to refer when compared to other ethnic groups and respondents who perceived their oral hygiene as poor. This finding is in line with a study from Hong Kong that reported patient referral being mostly associated with MPs' OH practices and perceived OH status.7 In Malaysia, the heavy workload in primary care clinics is mostly attributed to the low doctor-to-patient ratio, which may also contribute to poor patient referrals. Although the number of doctors in Malaysia increased by 7.7% in 2016, the doctor-to-population ratio remained high (1 doctor: 632 persons)24 despite the government target of 1 doctor: 400 persons in 2019.25

MPs also listed a few perceived barriers that they experienced during the management of DM patients. The most common barriers included referrals only being performed when patients requested them, no guidelines or SOPs from the dental fraternity for referral, and MPs lacking knowledge and awareness. Similar findings were reported in a study by Salleh et al., which found that 40% of the studied HCWs performed referrals when requested by their patients, whilst 44.4% of the HCWs requested a simple referral system.

**Limitations**

This study has certain limitations. First, the
convenience sampling method used in this study leads to generalisability issues. Notably, the findings cannot be generalised to the population of interest since this research was only conducted in a MOH public primary care setting in selected states within Peninsular Malaysia. There is also the possibility of under-representing the studied population and the potential for voluntary response bias. As of October 2017, a total of 104 FMSs in Malaysia were serving in primary care clinics in selected states. However, only 40 FMSs were involved in this study. Secondly, the number of MOs who participated in this study was higher than the number of FMSs. This is expected since there are only one or two FMSs posted in each primary care clinic and a higher number of MOs present in clinics. We are aware that a small sample size may affect the precision of the measurement. Nevertheless, this finding provides insights into the issue at hand. Third, the validity of the questionnaire used in this study was only tested using content and face validity. Since this study is considered a pilot study, the validity testing is deemed sufficient. However, it is recommended that the questionnaire be tested for construct validity for future use. Another limitation of this study is that the reliability of the questionnaire was not tested before data collection due to time constraints and anticipated difficulty in obtaining a sufficient sample size. This raised the question of whether or not the findings are reliable. To obtain some insights into the reliability of this study, internal consistency testing was performed on the data. It was found that the Cronbach’s alpha values were 0.24 (attitude), 0.40 (knowledge), 0.48 (awareness) and 0.73 (practice). Besides the practice domain, Cronbach’s alpha values for all other domains were below 0.7. Thus, the reliability of the questionnaire is questionable. Therefore, the findings of this study need to be interpreted with caution.

Since PD is a silent disease, not many patients realise that they are suffering from it. Our findings indicate that MPs have adequate knowledge about PD and its relationship with DM. Notably, this knowledge should be shared with DM patients through dental education provided during routine health education programmes. To reinforce this, future CPGs on DM management should include adequate information on the bi-directional relationship of both diseases and their complications. A proper SOP on DM patient referrals should also be emphasised in the CPG. Moreover, a simple referral format can be developed by dental policymakers. The incorporation of a specific module on the relationship between oral health and systemic diseases in the undergraduate medical curriculum may be beneficial and improve MPs’ KAP related to this relationship.

Conclusion
In this study, most MPs were aware of the association between DM and PD and had good knowledge of PD. Despite having good knowledge and awareness, most MPs had poor attitudes in their management of DM patients with PD. Additionally, patients may not benefit from the MPs’ awareness and knowledge since it was seldom put into practice. Thus, further measures to improve MPs’ attitudes and practices whilst enhancing patients’ knowledge on DM and PD should be explored. Moreover, identified barriers should be addressed accordingly.

Acknowledgements
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How does this paper make a difference to general practice?
• The importance of using a multidisciplinary approach to managing diabetes mellitus (DM) patients with periodontitis (PD) amongst Malaysian medical practitioners (MPs) (family medicine specialists and medical officers) is emphasised.
• Although MPs had good knowledge of PD, there was room for improvement in their attitudes and practices in managing these patients.
• An increase in MPs’ awareness of PD will lead to early PD detection and thus more favourable treatment responses for both DM and PD.
• Information on the management of DM patients with PD should be incorporated into the Malaysian Clinical Practice Guidelines (CPG) on the management of DM patients.
References


Maternal Obesity and Its Associated Factors and Outcomes in Klang Valley, Malaysia: Findings from National Obstetric Registry

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Keywords:
Maternal obesity, national obstetric registry, associated factors, ethnicity.

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Introduction:
The prevalence of obesity is increasing at an alarming rate across all populations and age groups, which has resulted in important public health concerns. According to the Global Burden of Disease (GBD) study, the number of overweight and obese people worldwide increased by nearly 3-fold over the past three decades (from 857 million in 1980 to 2.1 billion in 2013), with a higher prevalence of obese females than males. In Malaysia, the prevalence of overweight or obese adults continues to rise compared to National Health Morbidity Survey (NHMS) III in 2006 (28.6%, 14.2%), NHMS 2011 (29.4%, 15.1%) and NHMS 2015 (30.0%, 17.7%). Furthermore, Malaysia has the highest prevalence of obesity in South East Asia. According to NHMS 2019, one in two (50.1%) adults (aged 18 years and above) in Malaysia was either overweight (30.4%) or obese (19.7%), with a higher prevalence obese females (38.8%) than males (29.0%). Indian ethnicity had the highest prevalence of obesity (45.1%).

The increasing rate of obesity among women of reproductive age is a growing public health
issue. In Uganda, there has been a steady rise in the prevalence of overweight and obese women aged 15–49 years. A community-based cross-sectional study in Selangor showed that the prevalence of obesity among women in the reproductive age group (20–49) was 15.3%. The increasing rates of obesity among women of child-bearing potential (WOCBP) will cause more women to begin their pregnancy with a higher BMI, resulting in maternal obesity. These women are more likely to develop pregnancy complications, such as gestational diabetes, hypertensive disorders of pregnancy, and caesarean section delivery. The consequences of this higher maternal and neonatal morbidity, with its increased resource utilisation and significant cost, present critical challenges for maternity healthcare services related to the prevention and management of these risks.

The rise in global obesity rates has shown a similar trend among pregnant mothers. Globally, it is estimated that there are 38.9 million overweight and obese pregnant women. The majority of overweight and obese pregnant women live in upper and lower middle income countries, including Malaysia. In England, a cross-sectional study involving 619,323 births between 1989 and 2007 showed that maternal obesity is significantly increasing over time, having more than doubled from 7.6 to 15.6% over 19 years. In Malaysia, NHMS 2016 showed that the prevalence of maternal obesity was 14.6%, while mothers of advanced age (45–49) exhibited the highest prevalence of obesity (69.2%). The majority of obese mothers were of Malay ethnicity (16.8%), followed by Indian (15.6%) and Chinese (5.8%). The increasing prevalence of maternal obesity is an alarming issue since it represents a major challenge for obstetric practice.

According to the Centre for Maternal and Child Enquiries (CMACE) and the Royal College of Obstetricians and Gynaecologists (RCOG), in obstetric populations, an obese mother is defined as having a BMI equal to or greater than 30 kg/m², which is similar to that of the general population. Ideally, BMI should be calculated in the first trimester (i.e., before the mean maternal weight or body composition begin to change). The National Institute for Health and Care Excellence (NICE) antenatal care guideline (2008) and Kurowski recommend that maternal height and weight should be recorded for all women at their initial booking visit (i.e., at least 10–12 weeks gestation) to allow the calculation of BMI. This is because self-reported height is often overestimated and self-reported weight underestimated, particularly among obese women. Notably, this could lead to an inaccurate risk assessment during pregnancy.

Maternal obesity increases the risk of maternal death due to complications that arise during pregnancy and labour. According to the Confidential Enquiry into Maternal Child Health (CEMAH) 2003–2005 report, more than half of maternal deaths were due to direct or indirect causes of being either overweight or obese, with more than 15% of mothers being morbidly obese. Furthermore, the major direct causes of maternal mortality worldwide include haemorrhage, high blood pressure, infection and obstructed labour—all of which are associated with maternal obesity.

Published studies on maternal obesity in Malaysia remain in their infancy. Thus, there are very few studies regarding the prevalence of maternal obesity in Malaysia. A cross-sectional study of four antenatal clinics in Seremban showed that more than half of respondents were overweight or obese (60.6%). Moreover, another retrospective cross-sectional study of 72 health clinics in Selangor found that the prevalence of maternal obesity was 28.3%.

To our knowledge, there is no published study available on factors associated with maternal obesity by the Malaysian National Obstetric Registry (NOR). Therefore, this study aimed to examine the proportion, associated factors and outcomes of maternal obesity among pregnant women in Klang Valley using the NOR database. Identifying the proportion of maternal obesity among pregnant women and its associated factors can provide insights and facilitate health monitoring and evidence-based policies for preventive measures to improve maternal health and pregnancy outcomes. The findings from this study can also be used as a baseline to guide upcoming studies in this field as well as intervention programmes to improve maternal and fetal health, particularly in Malaysia.

**Methods**

**Study design and setting**

The present study applied a cross-sectional study design based on a retrospective data review between January and March 2018 in the Clinical Research Center (CRC) of Kuala Lumpur Hospital.
Data were collected from the Malaysian NOR. The NOR is an online registry that was created by the Ministry of Health in 2009 to monitor obstetric populations in Malaysia. A total of 14 tertiary hospitals and 1 district hospital across Peninsular Malaysia and East Malaysia contribute data to the NOR. Each hospital has a dedicated coordinator, Obstetrics and Gynaecology specialist or consultant and a nursing coordinator to monitor data entry. Klang Valley, which has two tertiary hospitals, was selected as the context for this study. Klang Valley is an urban conglomeration in Malaysia that is centred in Selangor, Kuala Lumpur, Putrajaya. Its surroundings and suburbs are naturally delineated by hilly areas and the Port Klang coastline.

Study Participants
The reference populations comprised pregnant women in Klang Valley. The study sample included pregnant women in Klang Valley who registered in the NOR 2015 and met the inclusion and exclusion criteria. In this study, the inclusion criteria were pregnant women who delivered a singleton newborn, booking done ≤ 12-week period of amenorrhea and had a cephalic presentation. The exclusion criteria were incomplete data with the absence of either weight or height data, unrealistic values due to erroneous data entry, the absence of gestational age during booking and those with pre-existing comorbidities (e.g., diabetes mellitus type 1 or type 2, chronic hypertension and chronic kidney disease) since pre-existing comorbidities may affect maternal and fetal outcomes analysis.

The sample size was calculated for each variable of associated factors for maternal obesity using the power and sample size calculation to compare two independent proportions. The largest estimated sample for each group was 2129 based on the proportion of normal BMI among pregnant women of Indian ethnicity (P₀) being 0.08, the estimated proportion of maternal obesity for Indian ethnicity (P₁) being 0.12, 5% type 1 error, 80% power, M (ratio between exposed and non-exposed subjects) of 2 and an additional 10% of missing data being applied in the data analysis.

Data Collection and Analysis
Notably, this study involved secondary data collection. The retrieved information includes socio-demographic details, including mother’s age, ethnicity, marital status, household income, and smoking status as well as obstetric characteristics (i.e., parity, maternal weight, height, BMI and period of amenorrhoea during booking).

BMI was calculated by weight in kilograms divided by height in metres squared. For descriptive analysis, the BMI values were classified into six categories based on the World Health Organization (WHO 1995) and Malaysian Clinical Practice Guidelines on Management of Obesity (MOH 2003) cut-off points. BMI values were calculated based on weights and heights documented at booking ≤ 12-week period of amenorrhoea. To determine the factors associated with maternal obesity and its outcomes, the WHO (1995) BMI classification was used as an international comparison due to limited evidence available for using different BMI cut-off points for pregnant Asian mothers. In this study, normal BMI was identified as 18.5–24.9kg/m². For the obese group, the BMI values for overweight and obese were grouped. Data for underweight individuals were excluded from further analysis since the main research question relates to maternal obesity and its associated factors.

The independent variables were categorised according to age (i.e., <35 and ≥35 years) and ethnicity was divided into five main groups (i.e., Malay, Chinese, Indian, other ethnicity and foreigner) according to NOR classifications. Murut, Bajau, Iban, Dusun, Melanau, Bidayuh, Kadazan, other indigenous groups in Sabah and Sarawak (East Malaysia), as well as Orang Asli (Peninsular Malaysia), were categorised as ‘other ethnicity’. Household income was classified as either low (<RM5000), middle (RM5000–9999) or high (≥RM10,000). Parity was classified as either nulliparous, multiparous or grand multiparous (parity ≥5). Marital status was classified as either married or single. Smoking status was divided into smoking and non-smoking. Booking details include maternal weight, height and BMI during booking. Maternal outcomes include gestational diabetes mellitus, hypertensive disorder in pregnancy, instrumental delivery, caesarean section and post-partum haemorrhage. Fetal outcomes include intrauterine growth restriction (IUGR), macrosomic baby, shoulder dystocia, preterm delivery, congenital abnormalities, low Apgar score and fetal death.
Statistical Package for Social Science (SPSS) version 22.0 statistical software was used for data entry and analysis. Descriptive statistics with mean and standard deviation (SD), frequency and percentages were calculated. Simple and multiple logistic regression analyses were used to determine factors associated with maternal obesity, while the association between maternal obesity and adverse maternal and fetal outcomes was assessed by using Pearson’s chi-squared test. Maternal BMI status was based on the WHO (1995) cut-off point for both analyses.

Multiple logistic regression was performed using the forward selection and backward elimination method, followed by the manual retention or removal of the independent variables remaining in the model based on their clinical importance. The output between models was then compared and the best model was selected. In this study, the single dichotomous outcome was coded as 0 for non-obese (normal) and 1 for obese (overweight and obese). Simple logistic regression was performed to select the variables for multiple logistic regression analysis, and only variables with a p-value <0.25 or clinical importance were selected. The factors included in the multiple logistic regression were age, ethnicity and parity. Multicollinearity between different predictor variables was checked using the variance inflation factor (VIF). Notably, a VIF value of <5.0 indicates no multicollinearity. All possible two-way interaction terms between significant variables were checked individually. The final model that gave the best fit and was parsimonious as well as biologically sound was selected. The adjusted odds ratio was estimated with a 95% confidence interval. A p-value of <0.05 was considered statistically significant. The association between maternal obesity and adverse maternal and fetal outcomes was assessed by using Pearson’s Chi-Square test to compare maternal and fetal outcomes between two categories of maternal BMI.

Ethical approval
Ethical clearance approval for this study was obtained from the Medical Research and Ethics Committee and Human Research Ethics Committee of Universiti Sains Malaysia (JePeM Code: USM/JePeM/17120720) and the Medical Research and Ethics Committee (MREC), Ministry of Health Malaysia (NMRR-17-3038-39050).

Results
Proportion of the study population
After applying the inclusion and exclusion criteria, the total sample retrieved from the registry for descriptive analysis included 2113 respondents. In the subsequent analysis for factors associated with maternal obesity, only 1964 respondents were retained for analysis since the underweight category was excluded.

According to the WHO (1995) BMI cut-offs points, 149 (7.1%) respondents were underweight, 881 (41.7%) were of normal weight, 604 (28.6%) were overweight, 336 (15.9%) were in obese class I, 98 (4.6%) were in obese class II and 45 (2.1%) were in obese class III. However, when the Malaysian Clinical Practice Guidelines on Management of Obesity (MOH 2003) were used, there was a marked increase in the proportion of the overweight by 2.7% and obese class I groups by 12.8% (Table 1).

<table>
<thead>
<tr>
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</tr>
</thead>
<tbody>
<tr>
<td>Underweight</td>
<td>&lt;18.5</td>
<td>149 (7.1)</td>
<td>Underweight &lt;18.5</td>
<td>149 (7.1)</td>
</tr>
<tr>
<td>Normal</td>
<td>18.5–24.9</td>
<td>881 (41.7)</td>
<td>Normal 18.5–22.9</td>
<td>554 (26.2)</td>
</tr>
<tr>
<td>Overweight</td>
<td>25–29.9</td>
<td>604 (28.6)</td>
<td>Overweight 23–27.4</td>
<td>662 (31.3)</td>
</tr>
<tr>
<td>Obese class I</td>
<td>30–34.9</td>
<td>336 (15.9)</td>
<td>Obese class I 27.5–34.9</td>
<td>605 (28.7)</td>
</tr>
<tr>
<td>Obese class II</td>
<td>35–39.9</td>
<td>98 (4.6)</td>
<td>Obese class II 35–39.9</td>
<td>98 (4.6)</td>
</tr>
<tr>
<td>Obese class III</td>
<td>≥40.0</td>
<td>45 (2.1)</td>
<td>Obese class III ≥40.0</td>
<td>45 (2.1)</td>
</tr>
</tbody>
</table>

Maternal characteristics
The maternal characteristics of the respondents are presented in Table 2. In general, the majority of respondents were of Malay ethnicity (78.3%), younger than 35 years old (85.0%), married (99.5%) and multiparous (55.1%). Furthermore, 83.1% had low income and only 0.2% of the study population were smoking.
Table 2. Maternal characteristics of pregnant women in Klang Valley (n = 2113).

<table>
<thead>
<tr>
<th>Variables</th>
<th>Total n (%)</th>
<th>Maternal BMI (n, %)</th>
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<tbody>
<tr>
<td></td>
<td>Total n (%)</td>
<td>Underweight (n = 149)</td>
<td>Normal (n = 881)</td>
<td>Overweight (n = 604)</td>
<td>Obese (n = 479)</td>
</tr>
<tr>
<td>Age (years)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>&lt;35</td>
<td>1814 (85.8)</td>
<td>144 (96.6)</td>
<td>772 (87.6)</td>
<td>517 (85.6)</td>
<td>381 (79.5)</td>
</tr>
<tr>
<td>≥35</td>
<td>299 (14.2)</td>
<td>5 (3.4)</td>
<td>109 (12.4)</td>
<td>87 (14.4)</td>
<td>98 (20.5)</td>
</tr>
<tr>
<td>Ethnicity</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Malay</td>
<td>1654 (78.3)</td>
<td>117 (78.5)</td>
<td>666 (75.6)</td>
<td>482 (79.8)</td>
<td>389 (81.2)</td>
</tr>
<tr>
<td>Chinese</td>
<td>60 (2.8)</td>
<td>3 (2.0)</td>
<td>35 (3.7)</td>
<td>18 (3.0)</td>
<td>6 (1.2)</td>
</tr>
<tr>
<td>Indian</td>
<td>173 (8.2)</td>
<td>14 (9.4)</td>
<td>63 (7.2)</td>
<td>52 (8.6)</td>
<td>44 (9.2)</td>
</tr>
<tr>
<td>Other ethnicity</td>
<td>68 (3.2)</td>
<td>1 (0.7)</td>
<td>29 (3.3)</td>
<td>18 (3.0)</td>
<td>20 (4.2)</td>
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<tr>
<td>Foreigner</td>
<td>158 (7.5)</td>
<td>14 (9.4)</td>
<td>90 (10.2)</td>
<td>34 (5.6)</td>
<td>20 (4.2)</td>
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<tr>
<td>Household income</td>
<td></td>
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<tr>
<td>High</td>
<td>33 (1.6)</td>
<td>1 (0.7)</td>
<td>14 (1.6)</td>
<td>13 (2.2)</td>
<td>5 (1.1)</td>
</tr>
<tr>
<td>Middle</td>
<td>324 (15.3)</td>
<td>24 (16.1)</td>
<td>129 (14.6)</td>
<td>98 (16.2)</td>
<td>73 (15.2)</td>
</tr>
<tr>
<td>Low</td>
<td>1756 (83.1)</td>
<td>124 (83.2)</td>
<td>738 (83.8)</td>
<td>493 (81.6)</td>
<td>401 (83.7)</td>
</tr>
<tr>
<td>Parity</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nulliparous</td>
<td>769 (36.4)</td>
<td>70 (47.0)</td>
<td>365 (41.4)</td>
<td>198 (32.8)</td>
<td>136 (28.4)</td>
</tr>
<tr>
<td>Multiparous</td>
<td>1156 (54.7)</td>
<td>74 (49.7)</td>
<td>463 (52.6)</td>
<td>344 (57.0)</td>
<td>275 (57.4)</td>
</tr>
<tr>
<td>Grand multiparous</td>
<td>188 (8.9)</td>
<td>5 (3.3)</td>
<td>53 (6.0)</td>
<td>62 (10.2)</td>
<td>68 (14.2)</td>
</tr>
<tr>
<td>Marital status</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Married</td>
<td>2103 (99.5)</td>
<td>148 (99.3)</td>
<td>878 (99.7)</td>
<td>600 (99.3)</td>
<td>477 (99.6)</td>
</tr>
<tr>
<td>Single</td>
<td>0 (0.5)</td>
<td>0 (0.5)</td>
<td>0 (0.5)</td>
<td>0 (0.5)</td>
<td>0 (0.5)</td>
</tr>
<tr>
<td>Smoking status</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non-smoking</td>
<td>2109 (99.8)</td>
<td>149 (100.0)</td>
<td>878 (99.7)</td>
<td>603 (99.8)</td>
<td>479 (100.0)</td>
</tr>
<tr>
<td>Smoking</td>
<td>4 (0.2)</td>
<td>0 (0.0)</td>
<td>3 (0.3)</td>
<td>1 (0.2)</td>
<td>0 (0.0)</td>
</tr>
</tbody>
</table>

Household income (<RM5000: Low; RM5000–9999: Middle; ≥RM 10000: High). 1 USD is equivalent to RM 4.16 as of 7th July 2021.

Factors associated with maternal obesity

A simple logistic regression showed that age, ethnicity and parity were associated with maternal obesity. Age 35 and above (crude OR 1.46, 95% CI: 1.13, 1.88, p = 0.004) as well as Malay (crude OR 1.80, 95% CI: 1.05, 3.07, p = 0.032) and Indian ethnicity (crude OR 2.10, 95% CI: 1.13, 3.87, p = 0.018) were significantly associated with maternal obesity. Regarding parity, multiparous (crude OR 1.46, 95% CI: 1.21, 1.78, p <0.001) and grand multiparous (crude OR 2.68, 95% CI: 1.89, 3.81, p <0.001) were also found to be significantly associated with maternal obesity. Notably, there were no significant associations between household income, marital status and smoking with maternal obesity. The results are summarised in Table 3.

Table 3. Simple logistic regression of factors associated with maternal obesity (n =1964).

<table>
<thead>
<tr>
<th>Variables</th>
<th>Regression coefficient B</th>
<th>Crude OR (95% CI)</th>
<th>Wald statistic (df)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;35</td>
<td>0.38</td>
<td>1.46 (1.13,1.88)</td>
<td>8.40 (1)</td>
<td>0.004</td>
</tr>
<tr>
<td>≥35</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ethnicity</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chinese</td>
<td>0.59</td>
<td>1.80 (1.05,3.07)</td>
<td>4.62 (1)</td>
<td>0.032</td>
</tr>
<tr>
<td>Malay</td>
<td>0.74</td>
<td>2.10 (1.13,3.87)</td>
<td>5.57 (1)</td>
<td>0.018</td>
</tr>
<tr>
<td>Indian</td>
<td>0.59</td>
<td>1.80 (0.88,3.68)</td>
<td>2.61 (1)</td>
<td>0.106</td>
</tr>
<tr>
<td>Foreigner</td>
<td>-0.19</td>
<td>0.55 (0.83,0.44)</td>
<td>0.36 (1)</td>
<td>0.546</td>
</tr>
<tr>
<td>Household income</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>High</td>
<td>0.03</td>
<td>1.03 (0.49,2.15)</td>
<td>0.01 (1)</td>
<td>0.935</td>
</tr>
<tr>
<td>Middle</td>
<td>-0.06</td>
<td>0.94 (0.47,1.91)</td>
<td>0.03 (1)</td>
<td>0.869</td>
</tr>
<tr>
<td>Low</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Parity</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nulliparous</td>
<td>0.38</td>
<td>1.46 (1.21,1.78)</td>
<td>15.11 (1)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Multiparous</td>
<td>0.99</td>
<td>2.68 (1.89,3.81)</td>
<td>30.10 (1)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Grand multiparous</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Marital status</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Single</td>
<td>-0.49</td>
<td>0.61 (0.15,2.46)</td>
<td>0.48 (1)</td>
<td>0.490</td>
</tr>
<tr>
<td>Married</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Smoking status</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non-smoking</td>
<td>-1.31</td>
<td>0.27 (0.33,2.61)</td>
<td>1.28 (1)</td>
<td>0.258</td>
</tr>
<tr>
<td>Smoking</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Multiple logistic regression analysis showed that maternal ethnicity and parity were significantly associated with maternal obesity (see Table 4). Malay ethnicity has 1.75 times the odds compared to Chinese to have maternal obesity (95% CI: 1.02, 3.00, p = 0.040), while Indian ethnicity has 2.06 times the odds compared to Chinese to have maternal obesity (95% CI: 1.11, 3.83, p = 0.021) when adjusted for parity. Moreover, multiparous has 1.46 times the odds compared to nulliparous to have maternal obesity (95% CI: 1.23, 1.73, p < 0.001), while a grand multiparous has 2.41 times the odds compared to nulliparous to have maternal obesity (95% CI: 1.78, 3.26, p <0.001) when adjusted for ethnicity.

Table 4. Multiple logistic regression of factors associated with maternal obesity (n =1964).

<table>
<thead>
<tr>
<th>Variables</th>
<th>Regression coefficient (B)</th>
<th>Crude OR (95% CI)</th>
<th>Wald statistic (df)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethnicity</td>
<td>Chinese</td>
<td>0.56</td>
<td>1.75 (1.02, 3.00)</td>
<td>4.13 (1)</td>
</tr>
<tr>
<td></td>
<td>Malay</td>
<td>0.72</td>
<td>2.06 (1.11, 3.85)</td>
<td>5.24 (1)</td>
</tr>
<tr>
<td></td>
<td>Indian</td>
<td>0.60</td>
<td>1.82 (0.88, 3.73)</td>
<td>2.63 (1)</td>
</tr>
<tr>
<td></td>
<td>Other ethnicity</td>
<td>-0.18</td>
<td>0.83 (0.44, 1.56)</td>
<td>0.33 (1)</td>
</tr>
<tr>
<td></td>
<td>Foreigner</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Parity</td>
<td>Nulliparous</td>
<td>0.38</td>
<td>1.46 (1.23, 1.73)</td>
<td>15.28 (1)</td>
</tr>
<tr>
<td></td>
<td>Multiparous</td>
<td>0.95</td>
<td>2.41 (1.78, 3.26)</td>
<td>27.61 (1)</td>
</tr>
</tbody>
</table>

Constant = -0.591.
Forward LR method was applied.
No multicollinearity and no interaction.
Hosmer-Lemeshow test: p-value = 0.066.
Classification table: 57.8% correctly classified.
Area under Receiver Operating Characteristics (ROC) curve was 59.0%.

Association between maternal obesity and adverse feto-maternal outcomes
The associations between maternal obesity and feto-maternal outcomes are summarised in Table 5. For maternal outcomes, there was a significant association between maternal obesity and hypertensive disorder in pregnancy (p = 0.025) and caesarean section delivery (p = 0.002). There was no significant association between maternal obesity and gestational diabetes mellitus and post-partum haemorrhage. For fetal outcomes, there was a significant association between maternal obesity and macrosomic infant (p <0.001). However, no significant associations for IUGR, shoulder dystocia, prematurity, congenital malformation, low Apgar score and fetal death were observed.

Table 5. Association between maternal obesity and adverse fetal and maternal outcomes (n=1964).

<table>
<thead>
<tr>
<th>Variables</th>
<th>Maternal BMI</th>
<th>X^2 statistics (df)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Normal n, (%)</td>
<td>Obese n, (%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>n = 881</td>
<td>n = 1083</td>
<td></td>
</tr>
<tr>
<td>Maternal outcomes</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gestational Diabetes Mellitus</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>830 (94.2)</td>
<td>998 (92.2)</td>
<td>3.20 (1)</td>
</tr>
<tr>
<td>Yes</td>
<td>51 (5.8)</td>
<td>85 (7.8)</td>
<td></td>
</tr>
<tr>
<td>Hypertensive disorder in pregnancy</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>874 (99.2)</td>
<td>1060 (97.9)</td>
<td>5.71 (1)</td>
</tr>
<tr>
<td>Yes</td>
<td>7 (0.8)</td>
<td>23 (2.1)</td>
<td></td>
</tr>
<tr>
<td>Caesarean section</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>534 (60.6)</td>
<td>580 (53.6)</td>
<td>9.86 (1)</td>
</tr>
<tr>
<td>Yes</td>
<td>347 (39.4)</td>
<td>503 (46.4)</td>
<td></td>
</tr>
<tr>
<td>Post-partum haemorrhage</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>878 (99.7)</td>
<td>1080 (99.7)</td>
<td>&gt;0.95*</td>
</tr>
<tr>
<td>Yes</td>
<td>3 (0.3)</td>
<td>3 (0.3)</td>
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</tr>
</tbody>
</table>
### Variables

**Maternal BMI**

<table>
<thead>
<tr>
<th>Variables</th>
<th>Normal n, (%)</th>
<th>Obese n, (%)</th>
<th>X² statistics (df)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Fetal outcomes</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>IUGR</td>
<td>No</td>
<td>869 (98.6)</td>
<td>1072 (99.0)</td>
<td>0.51 (1) 0.531</td>
</tr>
<tr>
<td></td>
<td>Yes</td>
<td>12 (1.4)</td>
<td>11 (1.0)</td>
<td></td>
</tr>
<tr>
<td>Macrosomia</td>
<td>No</td>
<td>872 (99.0)</td>
<td>1044 (96.4)</td>
<td>13.56 (1) &lt;0.001</td>
</tr>
<tr>
<td></td>
<td>Yes</td>
<td>9 (1.0)</td>
<td>39 (3.6)</td>
<td></td>
</tr>
<tr>
<td>Prematurity</td>
<td>No</td>
<td>846 (96.0)</td>
<td>1047 (96.7)</td>
<td>0.587 (1) 0.444</td>
</tr>
<tr>
<td></td>
<td>Yes</td>
<td>35 (4.0)</td>
<td>36 (3.3)</td>
<td></td>
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<tr>
<td>Congenital malformation</td>
<td>No</td>
<td>881 (100.0)</td>
<td>1081 (99.8)</td>
<td>0.505*</td>
</tr>
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<td></td>
<td>Yes</td>
<td>0 (0.0)</td>
<td>2 (0.2)</td>
<td></td>
</tr>
<tr>
<td>Low Apgar score</td>
<td>No</td>
<td>870 (98.8)</td>
<td>1066 (98.4)</td>
<td>0.356 (1) 0.573</td>
</tr>
<tr>
<td></td>
<td>Yes</td>
<td>11 (1.2)</td>
<td>17 (1.6)</td>
<td></td>
</tr>
<tr>
<td>Fetal death</td>
<td>No</td>
<td>879 (99.8)</td>
<td>1075 (99.3)</td>
<td>0.200*</td>
</tr>
<tr>
<td></td>
<td>Yes</td>
<td>2 (0.2)</td>
<td>8 (0.7)</td>
<td></td>
</tr>
</tbody>
</table>

*Fisher’s exact test.

### Discussion

**Proportion of maternal obesity**

The increasing prevalence of obesity is a serious matter that is having an impact on morbidity worldwide. Globally, the proportion of maternal obesity ranges from 10.1 to 17.9%. In the present study, 28.6% of pregnant women were overweight, while 22.6% of them were categorised under maternal obesity when using the WHO (1995) cut-off point. The proportion of maternal obesity in this study was higher (22.6%) than the national population survey (NHMS 2016), which reported a 14.6% prevalence. This was due to our study population being from two tertiary referral hospitals with specialised consultative care, where most higher-risk cases that have an association with maternal obesity (e.g., hypertensive disorder in pregnancy, gestational diabetes mellitus, etc.) were referred to. This resulted in a higher proportion of maternal obesity in this study when compared to the population-based survey. Nevertheless, we report a similar proportion of obesity among women (20.6%) to the general population in Malaysia (NHMS 2015), which has also been observed in another study.

This study also found that the proportion of overweight pregnant women increased to 31.3% and the proportion of maternal obesity increased to 35.4% when using the Malaysian Clinical Practice Guidelines on Management of Obesity (2003) cut-off point. A similar trend was found in Singapore, where the proportion of normal weight mothers was reduced by 16.1% and the proportion of overweight and obese increased by 7.4% and 8.8%, respectively, following the use of the Asian BMI cut-off point.

The WHO proposed a lower BMI cut-off point for Asians to indicate that the risk of cardiovascular mortality begins to rise at lower cut-off points in this general population. However, evidence for using different cut-off points among pregnant Asian mothers, as well as their associations (including complications), remains in its infancy.

**Factors associated with maternal obesity**

Our study shows that two major ethnic groups in Malaysia were associated with maternal obesity. In comparison to Chinese ethnicity as a reference group, Indian ethnicity is 2.1 times more likely to become obese in pregnancy, followed by Malay. These findings are in line with a study from Singapore, where Ying Pang, Loy, and Tan showing that maternal obesity was common among Malay (21.5%) and Indian (17.2%) when compared to Chinese (4.6%).

NHMS 2015 showed
a similar trend with a higher prevalence of obesity among women, those of Indian and Malay ethnicity; and the majority were at reproductive-age group resulting them to begin their pregnancy as obese once conceived. On the contrary, few studies have shown that maternal obesity was associated with minority ethnic groups. In the UK and Queensland, studies have shown an increased likelihood of being overweight and obese among black and indigenous women, respectively. Heslehurst et al. found no significant association between ethnicity and maternal obesity. However, the interpretation of this finding was limited since the numbers representing non-Caucasian populations were relatively low. The observed ethnic differences in the association between ethnicity and obesity may be attributed to differences in genetic predisposition as well as developmental and environmental factors. Additionally, Bahadoer et al. found that lifestyle- and pregnancy-related characteristics explained up to 40% of the associations. In our study, the diversity in cultural background and food consumption characterised by the three predominant ethnic groups in Malaysia (i.e., Malay, Chinese and Indian) results in a complex multiracial population. A mixed-method study of excessive weight gain among Malay people in Kelantan by Farhana et al. (2018) reported the perception of pregnancy as a time to gain weight freely, which is largely due to social norms of acceptability regarding excessive weight gain in pregnancy that commonly cite ‘eating for two’ and view pregnancy as a time to ‘enjoy’ or ‘relax’. A similar finding was observed among multi-ethnic pregnant women in Singapore. These norms result in post-partum weight retention and maternal obesity upon entering a subsequent pregnancy. Therefore, a targeted approach that is culturally sensitive is important in addressing this issue among multi-ethnic populations.

In this study, pregnant women who had higher parity were significantly associated with obesity. After controlling for ethnicity, grand multiparous women have a more than two times greater risk of becoming obese compared to nulliparous women. Another study showed similar results for the relationship between maternal obesity and increasing parity. This parity-related obesity burden can be explained by weight gain during pregnancy. A prospective cohort study of 638 mothers in Malaysia showed that 33.8% of respondents retained substantial weight (≥5kg above preconception weight), while gestational weight gain of ≥12kg was significantly associated with higher 6-month post-partum weight retention. Therefore, such women are more likely to exhibit maternal obesity when entering their next pregnancy. Furthermore, the requirement for energy storage depends on maternal pre-pregnancy body size. As such, the intake of excess energy beyond the requirements for a growing fetus would be stored, resulting in increased body fat composition with subsequent pregnancies.

Although our univariable analysis showed that age was associated with maternal obesity, it was not statically significant in the final model of logistic regression. Additionally, household income, marital status and smoking were not associated with maternal obesity, which has also been observed in a previous study. However, careful interpretation is required for these variables since there was a relatively small number of unmarried and smoking women represented in the data. In contrast, few studies have shown that advanced maternal age, low income, married status and smoking are associated with maternal obesity.

Maternal and fetal outcomes with maternal obesity

Our data suggest that there was a significant association between maternal obesity and hypertensive disorder in pregnancy (HDP). The prevalence of HDP in this study was lower when compared to findings in the Malaysian national population survey (5.8%) (NHMS 2016). Similar findings from a case-control study conducted in Tehran reported that obese mothers had a 4.5-fold greater risk of developing HDP. Additionally, Bodnar et al. reported that the adjusted risk of pre-eclampsia doubled at a BMI of 26 kg/m² and nearly tripled at BMI values of 30 kg/m² and above. The pathophysiology for the stated association was related to the low level of adiponectin, increased leptin level, insulin resistance, inflammatory upregulation, prothrombotic changes, abnormal placental vasculature and endothelial dysfunction found in obese women with hypertensive disorder, particularly severe pre-eclampsia. HDP was associated with both maternal and perinatal mortality and morbidity as well as an elevated risk of cardiovascular and metabolic disease later in life.

This study found that there was a significant association between maternal obesity and
caesarean delivery. The caesarean rate in this study was higher than the caesarean rate recommended by the WHO (10–15%).

Specifically, there was a significant association between maternal obesity and emergency caesarean section (p = 0.002) (result not shown). A meta-analysis involving 33 studies reported that the unadjusted ratios of caesarean delivery among overweight, obese and severely obese women were 1.46 (95% CI: 1.34, 1.60), 2.05 (95% CI: 1.86, 2.27) and 2.89 (95% CI: 2.28, 3.79), respectively, when compared to pregnant women of normal weight. In the US, the incidence of caesarean delivery increased by 28.3% with increasing maternal BMI compared to lean. Although the mechanism of maternal obesity affecting the labour process is not well established, studies have suggested that obese pregnant women have a significantly longer labour duration and slower progress at the early part of the first stage of labour (a condition known as labour dystocia), which increases their risk of caesarean delivery due to poor labour progress. This situation is contributed by poor myometrium contractility in obese mothers. Additionally, the increased pelvic soft tissue in obese parturient women causes cephalopelvic disproportionation, which is also a predisposing factor for caesarean events.

Our findings suggest that maternal obesity was associated with fetal macrosomia. This finding is supported by a systematic review and meta-analysis noting that obese mothers have a 2-fold greater risk of having macromesric babies. Tanaka et al. reported that maternal obesity is an independent predictor of macromesric infants, particularly from the third trimester through birth. Macrosomic infants are at higher risk of experiencing meconium aspiration, having a low Apgar score at 5 minutes, requiring assisted ventilation, subsequent NICU admission, and death. The fetal endocrine system contributes to fetal growth in response to maternal obesity. High insulin resistance was found in obese mothers and gestational diabetes mellitus mothers, which causes an increase in maternal nutrient availability (e.g., glucose and lipids) for the fetus. These resulting increases in neonatal insulin levels and other growth factor responses (e.g., leptin) lead to macrosomic infants. Furthermore, Sewell et al. reported that the macrosomic infants of obese mothers had a higher fat mass composition rather than lean body mass, thereby indicating that environmental (rather than genetic) factors pose a significant risk for offspring obesity and metabolic disorders later in life.

There was no significant association between maternal obesity and Gestational Diabetes Mellitus, post-partum haemorrhage, IUGR, prematurity, congenital malformation, low Apgar score and fetal death.

It is anticipated the burden of maternal obesity will rise in the future since the prevalence of obesity among women of reproductive age is increasing, as seen in NHMS 2019. Obtaining insights into ethnic differences in maternal obesity and prevalence is important for the development of tailored preventive strategies that aim to improve both maternal and fetal outcomes. Notably, this is crucial to achieving the aims of the United Nations Sustainable Development Goals (SDGs) by 2030. Concentrated efforts need to prioritise high-risk groups to maximise their pregnancy outcomes. Based on our findings, preventive strategies should focus on reducing pre-pregnancy maternal overweight status and obesity among women of reproductive age as a form of primary prevention by strengthening pre-pregnancy care. This would ensure that women do not enter pregnancy as overweight or obese. Regarding secondary prevention, pregnant women achieving adequate gestational weight gain (GWG) is crucial to prevent excessive GWG that can cause increasing BMI with increasing parity. Interventions should be tailored to the socio-cultural aspects identified in qualitative studies of multi-ethnic women in Malaysia—particularly Indian and Malay women—to ensure their effectiveness. Additionally, to improve the quality of care, a guideline for the management of maternal obesity in primary care is essential since there are currently no specific guidelines for managing obesity among women of reproductive age in the Malaysian Clinical Practice Guidelines on Management of Obesity, or among obese pregnant women in the Malaysia Perinatal Care Manual. One relevant example is ‘Queensland Clinical Guideline: Obesity in Pregnancy’. Furthermore, the Confidential Enquiry of Maternal Death (CEMD) in Malaysia needs to include specific analyses of maternal obesity as an attributable cause of maternal mortality so that the magnitude of the issue can be appreciated. Notably, this also applies to under-five mortality.

To our knowledge, this is the first study to report on the associations of both ethnicity...
In conclusion, the proportion of maternal obesity in Klang Valley based on NOR data was 22.6% when WHO (1995) cut-off points were used. This proportion increased by 12.8% upon using the Malaysian Clinical Practice Guidelines on Management of Obesity (2003) cut-off points. In this study, the factors associated with maternal obesity were Indian and Malay ethnicity and higher parity. Based on the univariable analysis, maternal obesity was associated with adverse fetal and maternal outcomes that include HDP, caesarean section delivery and macroscopic baby. To achieve the aims of the SDGs by 2030, we must maximise our efforts to identify and overcome this modifiable risk factor through culturally sensitive means to further reduce maternal and neonatal morbidity and mortality and break the detrimental cycle of metabolic derangement in our future generation.

Conflicts of Interest
This research received no funding. The authors declare that there are no conflicts of interest.

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References


A clinical audit of the diagnosis and management of chronic kidney disease in a primary care clinic

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Keywords: Chronic renal insufficiency, clinical audit, diagnosis, primary health care, Malaysia

Abstract
Introduction: This audit was performed to monitor the diagnosis and management of chronic kidney disease (CKD) according to the clinical practice guidelines (CPGs) of CKD 2018 in a primary care clinic.

Methods: Patients who attended the clinic from April to June 2019 and fulfilled the diagnosis of CKD were included in this study, except for those diagnosed with a urinary tract infection, pregnant women and those on dialysis. These criteria were set based on the CPGs. The standards were set following discussions with the clinic team members with reference to local guidelines, the 2017 United Kingdom National CKD audit and other relevant studies.

Results: A total of 384 medical records were included in this audit. Overall, 5 out of 20 criteria for processes and 3 of 8 clinical outcomes for CKD care did not meet the set standards. These included the following: documentation of CKD classification based on albumin category (43.8%); CKD advice (19.0%); dietitian referral (9.1%); nephrologist referral (45.5%); haemoglobin level monitoring (65.7%); overall blood pressure (BP) control (45.3%); BP readings for diabetic kidney disease (DKD) and non-DKD with > 1 g/day of proteinuria (≤ 130/80 mmHg, 37.0%); eGFR reduction of < 25% over the past year (77.2%). Identified problems included the absence of a CKD registry, eGFR and albuminuria reports, and a dedicated team, among other factors.

Conclusions: Overall, 8 out of 28 criteria did not meet the standards of CKD care set for this audit. The problems identified in this audit have been addressed. Moreover, strategies have also been formulated to improve the diagnosis and management of CKD in this clinic.

Introduction
Chronic kidney disease (CKD) is a common but silent and under-recognised condition. It has become a global public health concern due to the increasing number of patients presenting with this disease, its risk of progression to end-stage renal disease (ESRD) and the high morbidity and mortality associated with it.1 CKD has been recognised as a strong risk factor for coronary events, which can result in increased mortality and a significant financial impact for patients and communities.2 In recent years, the incidence of CKD among developing countries has increased, which suggests that the economic status of a country could be linked to the development or recognition of ESRD or both.3 In 2010, 2.6 million individuals received renal replacement therapy (RRT) worldwide, with estimates of between 2.3 to 7.1 million individuals requiring RRT but not receiving it.4 It has been projected that the number of people on dialysis will more than double (to 5.4 million) by 2030, with the largest growth expected in Asia.

In Malaysia, an article based on the Malaysian National Health and Morbidity Survey 2011 reported that 9.1% of adults were found to have CKD; however, only 4% were aware of their diagnosis.5 Notably, CKD prevalence increased from 9.1% in 2011 to 15.5% in 2018.6 The 29th Annual Data Report of the United States Renal Data System, which included data from 74 countries, revealed that Malaysia had the highest average annual increase in the overall rates of ESRD incidence from 2003 to 2016.7 In 2016, among young adults aged 20 to 44 years worldwide, Malaysia ranked second behind the United States in ESRD incidence rate (111 patients per million of the general...
A local study conducted in primary care clinics demonstrated that the monitoring and management of CKD complications and their associated cardiovascular risk factors were poor. Notably, the early detection and appropriate management of CKD have been shown to reduce the deterioration of kidney function by up to 50%. Hence, primary healthcare services serve an important and challenging role in preventing CKD and providing the quality clinical management of CKD patients. Therefore, current CKD management practices must be assessed especially in community-based primary care clinics. A clinical audit is an approach that can be used to assess care. For this reason, a clinical audit was conducted among adult CKD patients attending a primary care clinic.

Methods
This audit was conducted from 1st July to 20th September 2019 in a primary care clinic on a university campus in Gombak District, Selangor, Malaysia. Patients who visited the clinic from 1st April to 30th June 2019 and fulfilled the diagnosis of CKD were included in the study.

Clinic setting
The primary care clinic is located in the large district of Gombak, which has a total population of 629,971. The clinic has access to radiology, laboratory and referral services for other specialties. This clinic had an average of 80 patient attendances per day. All of the doctors working here are family medicine trainees and family medicine specialists. Patients normally see the same doctor for their appointments to ensure continuity of care. Patients who ‘walk in’ would be seen by any of the available doctors.

Sampling and recruitment
All patients aged 18 years and above who visited the clinic at least twice within the past year and had a renal profile or urine tests taken during the study period were screened for a diagnosis of CKD. In the CPGs, CKD is defined as either eGFR < 60 ml/min/1.73 m² and/or evidence of kidney damage that is present for more than 3 months. Markers of kidney damage include structural or functional abnormalities, decreased estimated glomerular filtration rate (eGFR), and albuminuria, which were screened from the electronic medical record (EMR) system by using the following keywords: chronic kidney disease, renal impairment, kidney transplant, polycystic kidney disease, hydrenephrosis, benign prostatic hyperplasia, renal artery stenosis, renal tubular acidosis, diabetes insipidus, potassium wasting, magnesium wasting, Fanconi syndrome, proteinuria, cystinuria, glomerulonephritis, pyelonephritis, cortical scarring and small kidney. The exclusion criteria included patients diagnosed with a urinary tract infection, pregnant women and ESRD patients on dialysis.

Defining standards for CKD diagnosis and management
The criteria for this audit were defined according to the 2nd edition of the Malaysian CPG on Management of CKD, which was published in 2018. The standard levels of performance for each of the criteria were set after discussions with the clinic team members based on the latest published standards of care, which include other local guidelines, the 2017 National CKD audit in the United Kingdom, a local audit by Iliza et al., and other relevant studies. The selected criteria represent the process and outcome measures of CKD management. Criteria for clinical care include the correct diagnosis of CKD with the documentation of classification based on the cause, glomerular filtration rate and albumin (CGA) category. Blood pressure (BP) measurement should also be performed at every visit. Other criteria for processes of care include obtaining a renal profile as well as urine albumin and glycosylated haemoglobin (HbA1c) levels at least once per year for patients with diabetic kidney disease (DKD). It was also agreed that the monitoring of CKD complications such as haemoglobin (Hb), corrected calcium (cCa), phosphate (PO4) and alkaline phosphatase (ALP) levels should be performed at least once per year for patients with CKD stage G3 and higher.

Regarding CKD retardation measures, angiotensin-converting enzyme inhibitors (ACEIs) or angiotensin receptor blockers (ARBs) should be prescribed if indicated, unless contraindicated. Statin should also be started on patients unless contraindicated. Medications known to be associated with CKD such as non-steroidal anti-inflammatory drugs (NSAIDs) and long-term proton pump inhibitors (PPIs) are also discouraged.
inhibitors (PPIs) should not be prescribed unless there is a clear indication. Patients with CKD should also be referred to a dietitian and CKD advice (avoidance or reduction of nephrotoxic agent exposure and CKD-specific dietary advice) should be provided and documented at least once in the past year. Patients who had indications for an ultrasound of the kidneys, ureter and bladder (KUB) (i.e., an eGFR reduction of > 5 ml/min/1.73 m² within 1 year or 10 ml/min/1.73 m² within 5 years, haematuria, symptoms or history of urinary tract obstruction, family history of polycystic kidney disease and age over 20 years, or when a renal biopsy is indicated) should have an ultrasound performed. Those who fulfilled the criteria for nephrology referral based on the CPGs (i.e., persistent heavy proteinuria [urine protein ≥ 1 g/day or urine protein: creatinine ratio (uPCR) ≥ 100 mg/mmol] despite optimal treatment, persistent isolated microscopic haematuria after excluding urogynaecological cause, persistent haematuria with proteinuria [urine protein ≥ 0.5 g/day or uPCR ≥ 50 mg/mmol], rapidly declining renal function [eGFR loss of > 5 ml/min/1.73 m² in 1 year or > 10 ml/min/1.73 m² within 5 years], eGFR < 30 ml/min/1.73 m² [eGFR categories G4–G5], resistant hypertension [failure to achieve target blood pressure despite three antihypertensive agents, including a diuretic], suspected renal artery stenosis, suspected hereditary kidney disease, pregnant or when pregnancy is planned, persistent abnormalities of serum potassium, unexplained cause of CKD) should also be referred.

The clinical outcomes of CKD care were defined as good control if the latest documented values were BP ≤ 140/90 mmHg for non-DKD with < 1 g/day of proteinuria; BP ≤ 130/80 mmHg for DKD or non-DKD with > 1 g/day of proteinuria; Hb A1c ≤ 7% for DKD; Hb ≥ 10.0 g/dL with cCa and PO4 within the normal ranges for CKD stage G3 or higher. The eGFR reduction target was set at less than 25% over the past year.

Results
A total of 897 patients attended the clinic during the study period and met the screening criteria. These patients were then reviewed for a diagnosis of CKD and the exclusion criteria. Overall, 513 patients were excluded since they did not receive a diagnosis of CKD or met the exclusion criteria. Thus, a total of 384 patients were included in the present study. Figure 1 presents a flow diagram of this study.

The mean age of the patients was 65.4 ± 9.3 years. Most of the patients were males (70.6%) and Malay (82.3%). The mean body mass index (BMI) was 28.5 ± 5.4 kg/m². Most of the patients were in CKD stage G3 and albuminuria category A1. More than half of the patients had concurrent hypertension and diabetes mellitus. The demographic and clinical characteristics of the audited patients are presented in Table 1.

Overall, 5 out of 20 criteria for CKD care processes did not meet the standards set for this audit. These include the documentation of CKD classification based on albumin category (43.8% versus the standard of 65%), haemoglobin level monitoring (65.7%), providing and documenting CKD advice (19.0%) and referral to dietitians (9.1%).
Moreover, referral to a nephrologist for patients meeting the referral criteria did not meet the set standard (45.5%). The measures of processes for CKD care are outlined in Table 2.

Overall, three out of eight criteria for the clinical outcomes of CKD care did not meet the set standards. These included overall BP control, BP ≤ 130/80 mmHg for DKD or non-DKD with > 1 g/day of proteinuria, and eGFR reduction of < 25% over the past year. The clinical outcomes of CKD care are presented in Table 3.

Problems identified in this audit included the absence of a CKD registry, eGFR and albuminuria reports, and a dedicated non-communicable team. Improvements could also be made to the EMR system, such as the creation of a compulsory section for diagnosis, automatic reminders, manual or electronic checklists, and order sets.

### Table 1. Socio-demographic and clinical characteristics of respondents (N=384).

<table>
<thead>
<tr>
<th>Socio-demographic and clinical characteristics</th>
<th>General n=384</th>
<th>Stage G1 n=23</th>
<th>Stage G2 n=75</th>
<th>Stage G3a n=138</th>
<th>Stage G3b n=106</th>
<th>Stage G4 n=38</th>
<th>Stage G5 n=4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years), mean ± SD</td>
<td>65.4 ± 9.3</td>
<td>58.4 ± 7.5</td>
<td>62.6 ± 10.2</td>
<td>65.7 ± 7.7</td>
<td>66.5 ± 9.9</td>
<td>71.1 ± 8.0</td>
<td>67.20 ± 98</td>
</tr>
<tr>
<td>Gender, n (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>271 (70.6)</td>
<td>10 (43.5)</td>
<td>13 (56.5)</td>
<td>109 (79.0)</td>
<td>55 (52.4)</td>
<td>5 (13.2)</td>
<td>3 (75.0)</td>
</tr>
<tr>
<td>Female</td>
<td>113 (29.4)</td>
<td>13 (46.5)</td>
<td>22 (43.5)</td>
<td>29 (21.0)</td>
<td>35 (37.6)</td>
<td>26 (86.9)</td>
<td>1 (25.0)</td>
</tr>
<tr>
<td>Ethnicity, n (%)</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Malay</td>
<td>316 (82.3)</td>
<td>14 (60.9)</td>
<td>67 (89.3)</td>
<td>116 (84.1)</td>
<td>85 (80.2)</td>
<td>32 (84.2)</td>
<td>2 (50.0)</td>
</tr>
<tr>
<td>Chinese</td>
<td>54 (14.1)</td>
<td>7 (30.4)</td>
<td>18 (24.3)</td>
<td>21 (14.9)</td>
<td>17 (16.0)</td>
<td>3 (7.9)</td>
<td>2 (50.0)</td>
</tr>
<tr>
<td>Indian</td>
<td>11 (2.9)</td>
<td>2 (8.7)</td>
<td>2 (14.3)</td>
<td>1 (6.5)</td>
<td>1 (9.0)</td>
<td>0 (0)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Others</td>
<td>3 (0.8)</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>1 (25.0)</td>
</tr>
<tr>
<td>BMI, mean ± SD</td>
<td>28.5 ± 5.4</td>
<td>28.4 ± 5.1</td>
<td>29.0 ± 6.1</td>
<td>28.2 ± 5.3</td>
<td>28.6 ± 4.7</td>
<td>27.4 ± 6.1</td>
<td>31.8 ± 5.1</td>
</tr>
<tr>
<td>eGFR, median ± IQR</td>
<td>50.8 ± 22.2</td>
<td>96.0 ± 8.0</td>
<td>73.0 ± 15.6</td>
<td>52.6 ± 7.2</td>
<td>38.5 ± 7.1</td>
<td>24.1 ± 5.96</td>
<td>12.2 ± 5.6</td>
</tr>
<tr>
<td>Albuminuria category, n (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>A1</td>
<td>161 (41.9)</td>
<td>8 (34.8)</td>
<td>26 (34.7)</td>
<td>76 (55.1)</td>
<td>13 (34.2)</td>
<td>13 (34.2)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>A2</td>
<td>110 (28.6)</td>
<td>13 (56.5)</td>
<td>50 (40.0)</td>
<td>31 (22.5)</td>
<td>8 (21.1)</td>
<td>8 (21.1)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>A3</td>
<td>93 (24.2)</td>
<td>2 (8.7)</td>
<td>18 (24.0)</td>
<td>24 (17.4)</td>
<td>15 (39.5)</td>
<td>15 (39.5)</td>
<td>4 (100)</td>
</tr>
<tr>
<td>Unknown</td>
<td>20 (5.2)</td>
<td>0 (0)</td>
<td>1 (1.3)</td>
<td>7 (5.1)</td>
<td>10 (9.4)</td>
<td>2 (5.3)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Diabetes mellitus only, n (%)</td>
<td>94 (24.5)</td>
<td>7 (30.4)</td>
<td>17 (22.7)</td>
<td>38 (27.5)</td>
<td>22 (20.7)</td>
<td>8 (21.1)</td>
<td>2 (50)</td>
</tr>
<tr>
<td>Hypertension only, n (%)</td>
<td>25 (6.5)</td>
<td>2 (8.7)</td>
<td>4 (5.3)</td>
<td>9 (6.5)</td>
<td>8 (7.5)</td>
<td>2 (5.3)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Diabetes mellitus and hypertension, n (%)</td>
<td>221 (57.6)</td>
<td>6 (26.1)</td>
<td>36 (48.0)</td>
<td>79 (57.2)</td>
<td>70 (66.0)</td>
<td>28 (73.7)</td>
<td>2 (50)</td>
</tr>
</tbody>
</table>

### Table 2. Measures of processes for CKD care.

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Frequency</th>
<th>Result (%)</th>
<th>Standard (%)</th>
<th>Achievement</th>
</tr>
</thead>
<tbody>
<tr>
<td>All patients who fulfilled CKD definitions were correctly diagnosed with CKD.</td>
<td>320/384</td>
<td>83.3</td>
<td>70</td>
<td>Achieved</td>
</tr>
<tr>
<td>Classification of CKD based on cause is documented.</td>
<td>334/384</td>
<td>87.0</td>
<td>50</td>
<td>Achieved</td>
</tr>
<tr>
<td>Classification of CKD based on GFR category is documented.</td>
<td>296/384</td>
<td>77.1</td>
<td>65</td>
<td>Achieved</td>
</tr>
<tr>
<td>Classification of CKD based on albumin category is documented.</td>
<td>168/384</td>
<td>43.8</td>
<td>65</td>
<td>Not Achieved</td>
</tr>
<tr>
<td>Blood pressure was recorded at all follow-up visits.</td>
<td>384/384</td>
<td>100</td>
<td>95</td>
<td>Achieved</td>
</tr>
<tr>
<td>A renal profile was performed at least once in the past year.</td>
<td>381/384</td>
<td>99.2</td>
<td>85</td>
<td>Achieved</td>
</tr>
<tr>
<td>A urine protein analysis was performed at least once in the past year.</td>
<td>362/384</td>
<td>94.3</td>
<td>90</td>
<td>Achieved</td>
</tr>
<tr>
<td>HbA1c was assessed at least once in the past year for DKD.*</td>
<td>264/268</td>
<td>98.5</td>
<td>50</td>
<td>Achieved</td>
</tr>
<tr>
<td>Hb was assessed at least once in the past year for patients with CKD stage G3 or higher.*</td>
<td>188/286</td>
<td>65.7</td>
<td>75</td>
<td>Not Achieved</td>
</tr>
<tr>
<td>Calcium was assessed at least once in the past year for patients with CKD stage G3 or higher.*</td>
<td>24/286</td>
<td>8.4</td>
<td>5</td>
<td>Achieved</td>
</tr>
<tr>
<td>Phosphate was assessed at least once in the past year for patients with CKD stage G3 or higher.*</td>
<td>23/286</td>
<td>8.0</td>
<td>5</td>
<td>Achieved</td>
</tr>
</tbody>
</table>
Table 3. Clinical outcomes of CKD care.

<table>
<thead>
<tr>
<th>Variables</th>
<th>Mean ± SD</th>
<th>Frequency</th>
<th>Result (%)</th>
<th>Standard (%)</th>
<th>Achievement</th>
</tr>
</thead>
<tbody>
<tr>
<td>BP</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>BP ≤ 140/90 mmHg a</td>
<td></td>
<td>72/108</td>
<td>66.7</td>
<td>50</td>
<td>Achieved</td>
</tr>
<tr>
<td>BP ≤ 130/80 mmHg b</td>
<td></td>
<td>102/276</td>
<td>37.0</td>
<td>50</td>
<td>Not Achieved</td>
</tr>
<tr>
<td>Total achieved target</td>
<td></td>
<td>174/384</td>
<td>45.3</td>
<td>50</td>
<td>Not Achieved</td>
</tr>
<tr>
<td>HbA1c a</td>
<td></td>
<td>7.6 ± 1.6</td>
<td>119/264</td>
<td>45.1</td>
<td>30</td>
</tr>
<tr>
<td>HbA1c ≤ 7%</td>
<td></td>
<td>174/384</td>
<td>45.3</td>
<td>50</td>
<td>Achieved</td>
</tr>
<tr>
<td>Haemoglobin a</td>
<td></td>
<td>12.9 ± 1.8</td>
<td>181/188</td>
<td>96.3</td>
<td>70</td>
</tr>
<tr>
<td>Mean ± SD, g/dL ≥ 10.0</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Corrected calcium a</td>
<td></td>
<td>2.32 ± 0.13</td>
<td>22/24</td>
<td>91.7</td>
<td>50</td>
</tr>
<tr>
<td>Mean ± SD, mmol/L Normal (2.20 – 2.55)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Phosphate a</td>
<td></td>
<td>1.29 ± 0.20</td>
<td>19/23</td>
<td>82.6</td>
<td>20</td>
</tr>
<tr>
<td>Mean ± SD, mmol/L Normal (0.81 – 1.45)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reduction of eGFR &lt; 25% in 1 year a</td>
<td></td>
<td>288/373</td>
<td>77.2</td>
<td>90</td>
<td>Not Achieved</td>
</tr>
</tbody>
</table>

a For non-DKD with < 1 g/day of proteinuria.
b For DKD or non-DKD with > 1 g/day of proteinuria.
* n is not equal to 384.

Discussion
This audit found that most of the processes and outcomes of care in the clinic were comparable to the aforementioned local and international standards of care. However, a few criteria did not meet the set standards. Among the processes of CKD care, the classification of CKD based on albumin category was not routinely documented. Our audit found that although test results were often reviewed, the documentation of CKD classification based on CGA and its monitoring were often missing. Notably, the renal profile and urine test reports in this institution do not include protein classification. Hence, doctors must manually classify albuminuria, which is time-consuming. This could explain why the documentation of this important clinical information often did not occur.
Haemoglobin levels were also not regularly monitored. Although the standards were met, calcium and phosphate levels were also not regularly assessed. These findings are consistent with results from the UK National CKD audit, which showed that monitoring for CKD complications was also not routinely performed. Moreover, most of these investigations (e.g., haemoglobin and ALP levels) were performed for other reasons, such as to investigate for prolonged fever or as part of default liver function tests. The monitoring of complications was more commonly performed in patients co-managed with a nephrologist. Therefore, appropriate and earlier referral to a nephrologist is important since it has been shown to reduce mortality and hospital stay, thereby achieving higher haemoglobin levels and improved dialysis preparation. However, less than half of the patients who warranted a nephrology referral were referred. One reason for this could be that the doctors were unaware of the deterioration in eGFR since it is not included as part of the renal profile report in this clinic. Since eGFR must be manually calculated, it could easily be skipped in a busy setting such as this. Moreover, this clinic does not have a dedicated non-communicable disease (NCD) team and respective registry that can help to identify and track the recommended monitoring of CKD patients. There is also a lack of automatic reminders in the EMR system and manual or electronic checklists available in the clinic to help remind doctors of necessary investigations and monitoring for CKD patients.

CKD advice and dietitian referrals were also not sufficiently documented in the medical records of audited patients. However, it is possible that CKD advice had been given to these patients but not documented in their medical records. Alternatively, such information could have been documented in the previous EMR system, which is no longer used in this clinic.

Despite ACEIs or ARBs being prescribed to more than 80% of patients, an inadequate number of patients achieved their target BP, especially for those with DKD or non-DKD with > 1 g/day of proteinuria. This finding is similar to a recent local study in which 41.9% of patients achieved their target BP. Possible reasons for not achieving the target BP may include medication non-adherence, polypharmacy, multiple co-morbidities and disease complications. Since this audit included elderly patients, individualised and more lenient targets might be used by the primary care doctors, as recommended by local hypertension guidelines.

There were also more patients who had an eGFR reduction of > 25% in 1 year than the standards set for this audit. As previously discussed, the doctors may not be aware of this deterioration since this clinic does not include eGFR results and albuminuria classification. Therefore, CKD retardation measures may not be adequately performed. It is also possible that doctors in this clinic may adopt a less aggressive approach to managing most of the elderly patients included in this audit due to the potentially harmful side effects that may occur.

On the positive side, this audit has also found several commendable achievements of this clinic in terms of CKD care. Regarding the care process, BP was measured and recorded in all patients at every visit over the past year. This achievement could be explained by the fact that all patients were required to go through a pre-assessment room, where blood pressure, heart rate, weight, height and waist circumference were measured. These measurements were performed before a patient could see a doctor. The clinic had managed to monitor the renal profile, urine protein and HbA1c of more than 90% of the audited patients, which exceeded the set standards. These results are similar to those of a previous audit in the UK. This may be due to the ease of access to in-house laboratory services, which ensured the timely return of test results. The percentage of patients attaining proposed glycaemic control was also found to be in line with the standard set. Among the 264 (98.5%) patients with DKD who had an HbA1c test performed in the past year, the mean HbA1c level was 7.6 ± 1.6%, with 119 (45.1%) having good glycaemic control. Notably, these results are slightly better than those of another local study. The audits, which were also conducted at primary care facilities, found that less than 40% of patients had HbA1c levels of ≤ 7.0%. The better results achieved in this audit could be due to the availability of more costly oral hypoglycaemic agents (e.g., SGLT2 inhibitors and glitins) and analogue insulin (e.g., aspart, glargine, and detemir). Furthermore, the patients in this audit may be better educated to manage their condition since the clinic utilises a self-management booklet to assist with their management.
Several recommendations were made during the presentation of the audit findings. Firstly, the clinic has been advised to establish a registry for CKD and NCD patients. Clinical registries have been shown to improve processes of care, healthcare utilisation and clinical outcomes. This will also facilitate a thorough evaluation of individual patient care, including timely reminders for important monitoring tests (e.g., annual eGFR and urine protein) and the assessment of CKD complications. Likewise, it is also important to develop an efficient clinical information system to establish a comprehensive registry for patients in this clinic. This may be achieved by introducing a required section for diagnosis based on the International Classification of Diseases (ICD)-10 for each medical record entry, which will make identifying patients with CKD easier. The layout of the clinical information system should also be simplified, especially to improve ease of access for pathology orders. Order sets are a type of clinical decision support system where a limited set of evidence-based tests exists for a series of indications. Notably, the incorporation of order sets into a computerised physician order entry system was shown to be effective in reducing the number of laboratory tests ordered, whilst also improving adherence to guidelines and achieving better treatment outcomes. This will be very helpful in the management of the patients in this clinic.

Next, the establishment of a dedicated NCD team in the clinic has also been proposed. An NCD team comprising multidisciplinary practitioners including medical specialists, pharmacists, dietitians, nurses and medical assistants has been shown to improve care, lower all-cause mortality, decrease hospitalisation rates and slow eGFR decline in patients with CKD. A prepared, proactive and trained multidisciplinary care team with clearly defined roles and responsibilities should be introduced along with regular updates on evidence-based care through ongoing medical education. In the management of chronic diseases, informed and active patients will improve their health outcomes. Therefore, a dedicated NCD team may help with patients’ empowerment in managing their health. Supplementary toolkits such as patient information leaflets or booklets, calendar flipcharts and quick reference guides can also be used to aid decision making during consultations. A quick reference guide that includes the target, monitoring requirements, nephrology referral and ultrasound indications based on local CKD CPGs and the clinical action plan for CKD by Kidney Health Australia was also developed by the audit team for the clinic and made available in every consultation room.

Finally, a further discussion with the pathology department was suggested with regards to the addition of calculated eGFR and albuminuria classification in their pathology reports. International guidelines have continuously recommended the reporting of calculated eGFR and the use of the Kidney Disease Improving Global Outcomes (KDIGO) 2012 classification of albuminuria in laboratory reports. The 2009 Chronic Kidney Disease-Epidemiology Collaboration (CKD-EPI) creatinine equation is currently recommended since it has shown superiority over the Modification of Diet in Renal Disease (MDRD) equation in Western and Malaysian populations. However, routine eGFR levels are currently absent in most pathology reports in Malaysia. It is hoped that the adoption of these recommendations will further improve CKD care in the clinic. A future audit will be able to gauge the success of changes implemented in the clinic.

Limitations
This audit was limited by the lack of a CKD registry in the clinic, which may have resulted in an inaccurate number of CKD patients being audited. Retrospectively auditing EMRs might not reflect the clinician-patient consultations where advice was given but not documented. There was also a change of the clinic’s EMR system in 2016, which resulted in difficulties retrieving previously recorded information (e.g., dietitian referrals).

Conclusion
In summary, 5 out of 20 criteria for CKD care processes and 3 out of 8 criteria for the clinical outcomes of CKD care did not meet the standards set for this audit. The problems identified in this audit have been addressed and strategies have been implemented to improve the diagnosis and management of CKD in this clinic. Another audit will be performed in the future to assess the outcomes of any implemented improvements.
Acknowledgements
The authors would like to acknowledge the IT department of the Faculty of Medicine, Universiti Teknologi MARA (UiTM) for providing the initial patient list for this audit. We would also like to extend our gratitude to all of the UiTM Primary Care Clinic staff who aided us in this study.

Competing interests
None declared.

Ethical approval
This study was approved by the Universiti Teknologi MARA Research Ethics Committee (REC/677/19).

Funding
None

How does this paper make a difference to general practice?
• Increases awareness and highlights the importance of the diagnosis and appropriate management of chronic kidney disease (CKD) in primary care settings in Malaysia.
• May serve as baseline targets for future audits on CKD.
• The recommendations from this audit may be considered in other primary care clinics to improve CKD management.

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References


Barriers to effective research supervision in clinical specialist training: Experience from a medical school in Malaysia

Yew Kong Lee, Chirk Jenn Ng, Joong Hiong Sim, Firdaus Amira, Chan Choong Foong, Wei Han Hong, Junedah Sanusi, Adrian Jia Hwa Lim, Christopher Chiong Meng Boey


Abstract

Introduction: A compulsory research component is becoming increasingly common for clinical residents. However, integrating research into a busy clinical training schedule can be challenging. This study aimed to explore barriers to research supervision in specialist training programmes from the perspectives of clinical supervisors and trainees at a Malaysian university hospital.

Methods: Qualitative interviews and focus group discussions were conducted (December 2016 to July 2017) with clinical supervisors (n=11) and clinical trainees (n=26) utilising a topic guide exploring institutional guidelines, research culture and supervisor-student roles. Interviews were transcribed verbatim and analysed thematically to identify barriers to research supervision.

Results: Supervisors and trainees from 11 out of 18 departments participated. Both clinical supervisors and trainees struggled to successfully integrate a compulsory research component into residency training. Among the reasons identified included a lack of supervisory access due to the nature of clinical rotations and placements, clashing training priorities (clinical vs research) that discouraged trainees and supervisors from engaging in research, poor research expertise and experience among clinical supervisors hampering high-quality supervision, and a frustrating lack of clear standards between the various parties involved in research guidance and examination.

Conclusion: Both clinical supervisors and trainees struggled to successfully integrate a compulsory research component into residency training. This was not only an issue of resource limitation since questions regarding clinical priorities and unclear research standards emerged. Thus, institutional coordinators need to set clear standards and provide adequate training to make research meaningful and achievable for busy clinical supervisors and trainees.

Introduction

A mandatory research component is becoming increasingly common in medical specialist training. However, numerous barriers to research exist in specialist training, including insufficient time to conduct research, low interest and inadequate research skills. Previous studies have reported that specialist trainees find research difficult and approach it reluctantly. From a pedagogical perspective, these trainees are now re-entering (postgraduate) medical training as adult learners—for whom engagement with a topic is essential to motivation. Therefore, if trainees are more motivated to become ‘clinician-specialists’ instead of ‘clinician-scholars’, the mandatory research component might fail to fulfil the learning needs of these adult learners. Studying the Malaysian context will be useful for discipline planning to establish more formal research standards.

This study examines specialist training within an Asian context in Malaysia. Clinical specialist training programmes in Malaysia were established in the 1960s as master’s level courses in public universities. Due to the master’s accreditation, clinical trainees are required to conduct research as part of Malaysian master’s standards criteria.

Keywords: Supervision, research, graduate medical education

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Methods  
Research design  
Since little was known about this topic within a non-Western context, we used a qualitative design employing an interpretive-descriptive approach to explore the topic of research supervision. We obtained the views and perspectives of supervisors and trainees through in-depth interviews (IDIs) and focus group discussions (FGDs), which were then interpreted and described using thematic analysis. IDIs were used for clinical supervisors since in-depth interviews are suited to expert participants who can provide an overview of the topic. FGDs were chosen for the trainees to capitalise on their shared experiences and be triggered to discuss their research experience in greater detail.  

Setting  
This study was conducted in the Faculty of Medicine at the University of Malaya. This public university has the highest number of clinical specialist training programmes, with 18 clinical departments conducting 27 4-year clinical masters’ programmes. These programmes can either be fully on-site at the university hospital or off-site/on-site with trainees spending the first 2 years of clinical training in public hospitals before returning to the university hospital. Trainees are required to complete a research project and submit a dissertation to obtain their master’s degree. Dissertations are marked within the respective departments.  

Sampling and recruitment  
We used purposive sampling to recruit participants from each clinical programme. A total of 11 supervisors and 26 trainees agreed to participate in the study. For the supervisors, we interviewed the respective departmental postgraduate coordinators or lecturers who had experience in supervising research. For clinical trainees, we only included candidates who had already started their research project (usually in the third or fourth year).  

Data collection  
The interviews and FGDs were conducted with interview guides based on Soren’s domains of research supervision framework, which focuses on institutional guidelines, research culture, functional supervision (i.e., research mentorship), and student-supervisor roles. For supervisors, supervisory training and experience were also explored. The guides are provided in Appendices 1 and 2.  

We conducted data collection between December 2016 and September 2017. The sessions were audio-recorded with a note taker present.  

Data analysis  
We used a thematic approach to data analysis. The audio recordings were transcribed verbatim. Next, five research team members (YKL, JHS, CCF, WHH and AJHL) jointly coded a transcript line-by-line and the codes were then collapsed to form larger categories. This formed an initial coding tree. Subsequently, two researchers (YKL and AJHL) used the coding tree to code the remaining transcripts. Any discrepancies in the coding were resolved by discussion until consensus was reached. The codes were discussed at two research team meetings. Having multiple members check and discuss the data helped to increase trustworthiness and avoid bias from a single perspective. The team members were a mix of clinicians and education researchers comprising a health psychologist, a primary care medicine specialist, a faculty-level postgraduate coordinator, an academic development researcher and medical education researchers. Data analysis was conducted iteratively, with data collection continuing until no new information was gathered or data saturation was reached.  

Ethics  
This study received ethics approval from the University of Malaya Medical Centre Medical Ethics Committee (Reference: MECID.NO: 20166-2530).  

Results  
Overall, 11 out of the 18 clinical departments participated in the present study. A total of 11 lecturer IDIs and 7 clinical trainee sessions (n=5 FGDs, n=2 IDIs) were conducted. Participant demographics are reported in Table 1.
Table 1. Participant demographic information.

<table>
<thead>
<tr>
<th>LECTURERS</th>
<th>n = 11</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female</td>
<td>7</td>
</tr>
<tr>
<td>Male</td>
<td>4</td>
</tr>
<tr>
<td>Age (range in years)</td>
<td>40–47</td>
</tr>
<tr>
<td>Completed a postgraduate research degree (e.g., PhD, DPhil)</td>
<td>3</td>
</tr>
<tr>
<td>Postgraduate coordinator experience (range in years)</td>
<td>1–6</td>
</tr>
<tr>
<td><strong>Position</strong></td>
<td></td>
</tr>
<tr>
<td>Department clinical postgraduate coordinator</td>
<td>10</td>
</tr>
<tr>
<td>Coordinator for postgraduate research</td>
<td>1</td>
</tr>
</tbody>
</table>

**POSTGRADUATE CLINICAL TRAINEES**

<table>
<thead>
<tr>
<th>n = 26</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female</td>
</tr>
<tr>
<td>Male</td>
</tr>
<tr>
<td>Age (range in years)</td>
</tr>
<tr>
<td>Pursuing an academic medical career (i.e., sponsored by a public university)</td>
</tr>
<tr>
<td>Time between starting training and beginning research* (range in years)</td>
</tr>
<tr>
<td>Number of research supervisors per trainee (range)</td>
</tr>
<tr>
<td>Clinical and research supervisors are different people</td>
</tr>
</tbody>
</table>

* Defined as the calendar year in which the respondent began their research project after starting their master’s programme.

Four main themes emerged as barriers to research supervision in clinical master’s programmes: i) Access to research supervision; ii) Training priorities (clinical vs research); iii) Research expertise; iv) Varying research standards.

**Limited access to research supervision**

Poor accessibility to research supervision proved to be a significant barrier, especially for off-site/on-site programmes where trainees were away from the university for the first 2 years. Although this off-site placement was important for the development of clinical skills, both trainees and supervisors said that the distance between supervisor and trainee made it difficult for trainees to receive training and guidance on research since their contact time was limited.

‘I think they (the trainees) are busier outside. Their clinics are heavier. We can get some allocated time for classes and things like that. But I think in KKM (Ministry of Health settings), maybe not so much.’ *Trainee (FGD/CT_1)*

‘For those off-campus, our programme is 4 years; 2 years out, 2 years in. So, for the 2 years out, it is probably hard to communicate with the on-campus supervisors.’ *Clinical supervisor (IDI/CL_1)*

Some programmes allowed students to start their research projects under their off-site supervisor. However, these projects often required corrections after students had returned to the university. Thus, some departments required students to present their research proposals shortly after their return to campus in order to monitor (and correct) these projects.

‘We (trainees) have an off-campus supervisor and an on-campus supervisor. So, my research is conducted in my off-campus centre at S_g Hospital. Basically, I get most of my info from my off-campus supervisor, not so much from my on-campus supervisor, because my research is being done off-campus.’ *Trainee (FGD/CT_2_1)*

‘Some of them (trainees) have been reined back because they have not touched base with their academic supervisor. They have done their own thing in the Ministry of Health and we then found that actually it was not up to standard.’ *Clinical supervisor (IDI/CL_2)*

**Training priorities (clinical vs research)**

Participants pointed out that the primary purpose of the clinical masters training programme is to graduate trained specialists. Some respondents said that research was never given any prominence during earlier undergraduate or house officer training. Unsurprisingly, trainees said that they did not see the relevance of the research component. In courses where there were parallel specialist qualification routes (e.g., taking external fellowship examinations), trainees preferred those routes over the master’s programmes since there was no compulsory research component.

‘If you are destined to be a doctor, research is never a part of it. It is only a part of it when you enter a specialisation. When you do your housemanship, you are not really encouraged to do it… So, it is all about clinical, clinical, clinical work.’ *Clinical supervisor (IDI/CL_4)*
‘Many medical officers that would join the MRCP (Member of the Royal College of Physicians) and they would not need to produce a thesis. And you know, that is the benefit so to say for them. The benefit is obviously that you have less to work on… and some people will say, you know, the research component in the masters is a threat in itself’. 
Clinical supervisor (IDI/CL_5)

Some clinical coordinators echoed that research was not a priority. One felt that the research component could impair the trainees’ clinical exam preparations and that research should not distract them from the exams. Some were frustrated at having to supervise research since they preferred clinical training and did not like research.

‘I have to say, my concentration is mainly on producing good clinical doctors… I’m not producing a scientist; I’m producing a clinician with an open mind’. Clinical supervisor (IDI/CL_5)

‘I’m a clinician, not a researcher. For me, the only reason I’m doing it, to be frank, is because I’m at the university. The university requires you to do it, so I do it. That’s all. My main work is doing clinical work. I think if you ask 10 clinicians, they will tell you the same thing’. Clinical supervisor (IDI/CL_3)

A lack of research expertise

Clinical lecturers are not required to possess a postgraduate research degree (e.g., PhD or MD). Thus, they may not be skilled or confident enough to supervise postgraduate research. To overcome this, research supervision in some departments was delegated to more ‘research-oriented’ lecturers.

‘But for research, they (trainees) can take anybody. So, there is no specific research supervisor… Some (lecturers) are very clinically inclined, and they themselves don’t do that much research, so they do not supervise. So, these are the ones who do not get any students. So, those who are more research-oriented will get more students’. Clinical supervisor (IDI/CL_7)

For off-site programmes, participants noted that hospital-based clinical supervisors did not give much attention to research. Another issue was a mismatch between trainees’ and supervisors’ research areas and interests. This resulted in off-site trainees initiating projects based on their off-site supervisor’s interests, which then had to be continued with their on-site supervisors.

‘KKM (Ministry of Health) is not so happy because we (the University) greatly emphasise so much on research. They said most of them did not do research anyway’. Clinical supervisor (IDI/CL_7)

‘My topic is usually based on my external or off-campus supervisor. So, it’s a bit difficult because my topic is a bit more relevant to my off-campus supervisor. So, my on-campus supervisor cannot contribute at much as my off-campus supervisor. So, most of the time I will go to my off-campus supervisor’. Trainee (FGD/CT_2_1)

Varying standards of research

In general, departments could be divided into two types according to their research standards: easy (where most—if not all—of the trainees pass the research component) and difficult (where trainees were strictly examined and failed if they did not meet the examination standards). In the former, standards for research were generally minimal, and trainees who demonstrated a general understanding of the research process would pass. In the latter, trainees became disgruntled due to varying standards since this significantly affected their likelihood of passing. They pointed out three types of discrepancies that were faced: i) between supervisors (e.g., some expected more complex methodologies); ii) between supervisors and examiners (e.g., failure due to a discrepancy between supervisors’ and examiners’ standards); iii) between supervisors and research experts (e.g., receiving different advice when consulting statisticians).

‘Sometimes, during the (research) presentation, I feel like it’s like a closed circuit; you and your supervisor in one (circuit) and now (during the presentation) it is open. Communication is not occurring between other examiners or lecturers, or between them and the statistician. [It] is like you are alone. [It] is like [the rest of them] totally do not communicate sometimes, I feel. Like, some say the statistics should be like this but then the lecturer says, “No, you have to interpret it this way”. But they never meet [all] three together. You are just stuck in between’. Trainee (FGD/CT_3_1)

‘Different lecturers have different opinions…some of the tests, like the reliability test—a simple thing like this—some say you don’t have to do it. You know, different opinions. So, there is no proper guide and I think there is no standard on what to do’. Trainee (FGD/CT_3_2)
Varying standards led to confusion and frustration among trainees who expected their supervisors to be able to guide them. Without good early guidance, it could be too late for students to raise questions after the data collection had been performed. Although trainees were not worried about passing or failing in departments where minimal standards were employed, external examiners noted that the research fell short of their standards.

Actually, there was one candidate who didn’t count the sample size. So, I was wondering if, let’s say, you know, he did it wrong from the beginning, why didn’t the supervisor say anything about it? Trainee (CT_3_2)

There were times we found out that we have an oral progress presentation where all the faculty will be present. That’s when you are asked, “How come you didn’t do this step and we do this step?” And you can’t say, “I’ve been told by my supervisor not to do that step.” Trainee (CT_3_4)

I think one of the things is that, uh, now they try to initiate things (research support) to be more structured because there were remarks from the past external examiner that our student theses were not—I mean for them—up to their expectation. Trainee (IDI/CT_4)

Discussion And Conclusion

This study shed light on how contextual issues played an important role in the emergence of barriers to research. The issues of research access, priority, expertise and standards found in this study are likely found in most clinical specialist training programmes.1,2,13 Thus, discussions on these issues are relevant to programmes elsewhere.

The participants in our study highlighted the lack of access to research supervision, especially when off-site. Barriers to access have been raised in other hospital-based research settings, where trainees recognise that being in the same location is key to having more supervisor access.14 Thus, in settings where students and supervisors are in different locations, it is important to strategise about how trainees can best utilise ‘off-site’ time for research. For example, universities can look into forming collaborations with hospital clinical research centres, where research-trained staff could provide students with on-site research support. Moreover, clinical (i.e., hospital-based) supervisors could also contribute to research by generating researchable areas from their clinical setting and experience. However, academic supervisors may need to strike a balance between academic research, health-system-based research and clinical audit. Furthermore, off-site trainees and academic supervisors should leverage the use of online video-conferencing platforms to increase access and meeting frequency. This will also help to reduce the difference in the amount of teaching received on research techniques between off-site and on-site trainees.

The question about training priorities (i.e., the priority and place of research in clinical master’s training) was pertinent to our study. As mentioned in the introduction, Malaysia’s inclusion of compulsory research in specialist training programmes was a master’s standards decision made 40 years ago. This contrasts with the more recent inclusion of research in other countries, which generally aims to develop clinician-scholars who advance the field.16 However, trainees apparently fail to link the importance of compulsory research with their experience as medical practitioners. Engagement in learning only occurs when adults know why they need to learn new things (i.e., research), which might be exacerbated when the learning is against their internal motivation (i.e., compulsory).7 Understanding the context of how views are formed is the first step. The next step involves re-framing clinicians’ views of research in health systems like Malaysia’s, where capacity building for service delivery is the dominant narrative and policy thrust. In this context, service orientation could be leveraged by reminding trainees and supervisors that conducting research feeds into a positive cycle of clinical skills improvement. Academic role models who actively translate research results into practice are important in this regard.

Another concern was the lack of research expertise available in the clinical setting. Others have also reported a paucity of experienced researchers in specialist training centres due to a historical lack of hiring or producing clinical staff with research experience.1 If formal standards for supervisors are eventually introduced, there will be an insufficient number of qualified supervisors, which would lead to the unequal distribution of supervisory responsibilities. Thus, policies and strategies must be put in place by institutions to train existing clinicians for research supervision along with the tandem requirements for research skills (e.g., implementing structured research
skill programmes for lecturers and providing training opportunities for postgraduate research degrees) and supervisory skills (e.g., supervising research projects, advising on when or how to seek help, co-supervision and knowing the minimum standards required for a student to pass their research component). With skilled lecturers in place, adequate preparation should be provided for students before embarking on their research project through multi-faceted development programmes that can include training workshops, facilitated lecturer access and project presentation meetings. In recent years, more training workshops have specifically targeted clinical trainees. To further facilitate this process, train-the-trainer workshops should be conducted to enhance the skills of lecturers in guiding their trainees.

The last issue was that of setting standards for research in clinical programmes. Rothberg et al. (2014) observed that the requirements for scholarly activity in US graduate medical programmes have been purposely left vague to allow each programme to fulfil the requirements in their own way. However, our study shows that there are training contexts in which research standards need to be clearer. If research forms part of the accreditation for clinical specialist training (e.g., as in Malaysia, Singapore and South Africa), a clear set of standards would be beneficial and should outline whether or not the standards of research in a clinical master’s are equal to those of a master of science degree. In the last few years, major reviews of the national postgraduate medical training curriculum have been conducted by most clinical specialities. These have involved looking at the standards required for the research component of clinical training programmes. Another context in which clear standards are required includes clinician-scholar programmes such as the academic clinical fellowship programmes in the United Kingdom, where doctors interested in pursuing careers in academic medicine gain both a clinical specialist qualification and a PhD. If exposure to scholarly activity is the goal of the research component, a full-blown research project is unnecessary and participation in an ongoing research project would suffice. Another model would be to provide residents with protected research time via an additional year for research. Notably, this has been shown to double publication output in a 5- vs 6-year residency program. Thus, the goal of research in a clinical training programme must be clear before standards can be set accordingly.

This study had several limitations that might have affected the study findings. For example, not all departments were represented in this study since some chose not to participate. Thus, there may be barriers or facilitators to research supervision that were not captured.

Research supervision within clinical training programmes can be frustrating for both trainees and supervisors. This struggle is not just an issue of time or resource limitation since questions about clinical priorities and unclear research standards emerged in this study. Identifying and addressing these contextual issues is important to ensure that trainees can engage in meaningful research within clinical training programmes.

Acknowledgements
We wish to thank all of the participants who took part in the study. We also thank the Faculty of Medicine, University of Malaya for funding the study.

Conflicts of interest
There are no conflicts of interest to declare.

How does this paper make a difference to general practice?
• There is a growing emphasis on incorporating research into postgraduate general practice programmes.
• This study identified challenges in 11 specialist training programmes from both lecturers and students at a Malaysian university, including the postgraduate family medicine programme.
• Barriers included a lack of supervisory access due to off-site clinical rotations, clashing training priorities (clinical vs research), poor research experience among clinical lecturers and a lack of clear research standards.
• These barriers need to be addressed in general practice postgraduate education programmes to improve the research experience of students.
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APPENDIX

APPENDIX 1: Topic Guide for Postgraduate Clinical Supervisors

Introduction

1. How long have you been supervising the research component of clinical master’s students?
2. How many students are you supervising now?
3. How has your experience of supervision been?

We would like to ask you about your practice of research supervision.

Institutional

1. How do you usually supervise your students (research skills)? Does your department have a set of guidelines on research supervision (e.g. frequency of meetings, supervisory forms, supervision contracts?)
   a. Do you co-supervise? If yes, how do you decide the supervisory roles?
2. Is there anything that hinders your supervision?
   a. Probe – time constraints/multiple roles
   b. Probe – too many rules and regulations
   c. Probe – lack of support

Research culture/ Critical thinking

1. What else do you teach your students besides research skills to help them to be better researchers?
   a. Ethics
   b. Grant application processes
   c. Dissemination (conferences)
   d. Scientific communication (e.g. language for grant writing, conferences)
2. What is your expectation of the student’s research?
   a. Goal of a research component (pass the student? publication?)
   b. How does this affect your supervision?
   c. How do you deal with conflict with the student?
   i. What is the source of these conflicts?

Functional supervision

1. Do you teach them research skills i.e. skills needed to plan, conduct and write up a thesis (one-to-one, workshops)? If yes, how?
2. How do you monitor the progress of your student?
   a. How do you give feedback to your students? Do you ask for feedback from your students?
3. How do you motivate your students to do research?
   a. Barriers to conducting research (emotional, disinterested, personal problems, stressed over doing research)
4. How do you prepare your students for their research/thesis exams?
   a. Do you explain to the students what the thesis examination format is like?
5. What if your students fail their research exams? How do you support them?
Student-Supervisor Roles and Relationship

1. Does your relationship with the student change over time? Could you describe your relationship with your student?

2. Do you approach clinical and research supervision differently? If yes, how?
   a. Do you switch roles between clinical supervision and research supervision? If yes, how?
   b. Do you blend research and clinical supervision (e.g. clinical justification, recommendations for future research) when supervising the same student?
   c. What would you say is your priority? Why do you say so?
      i. Do you think a research component is necessary for a clinical master's program?

3. How do you feel about research supervision?
   a. Probe: Enjoyable or not? Meaningful or not? And why?
   b. How does your experience of research supervision compare to clinical supervision?

4. What benefits do you get out of this research supervision?

Training for research supervisors

1. Are there any criteria for becoming a research supervisor in your department?
2. Have you gone for any training to become a research supervisor?
3. What support do you need as supervisors?
   a. Support for supervisors
   b. Support for students

APPENDIX 2: Topic Guide for Postgraduate Clinical Trainees

Introduction

1. How long have you worked on the clinical master's research component?
2. How many supervisors do you have now?
3. How has your experience of supervision been?

We would like to ask you about your experience of research supervision.

Institutional

3. Can you tell me how your supervision for the research component of your masters has been? Does your department have a set of guidelines on research supervision (e.g. frequency of meetings, supervisory forms, supervision contracts?)
   a. Are you co-supervised? If yes, how do your supervisors work with you?

4. Is there anything at your department that hinders your masters research?
   a. Probe – structure of masters programme
   b. Probe – too many rules and regulations/unclear rules and regulations
   c. Probe – Lack of support

Research culture/ Critical thinking

3. What else has your research supervisor taught you besides research skills to help you to become a better researcher?
   a. Ethics
   b. Grant application processes
   c. Dissemination (conferences)
   d. Scientific communication (e.g. language for grant writing, conferences)
4. What do you think is the expectation for the research that you are doing?
   a. Goal of a research component (pass the thesis exam? publication?)
   b. How does this affect how you approach the research component?
   c. Have you experienced any conflict with your supervisor?
      i. If yes, what is the source/s of these conflicts?

**Functional supervision**

6. Did your supervisor teach you research skills i.e. skills needed to plan, conduct and write up a thesis
   a. How did he teach you? i.e. one-to-one, workshops

7. Does your supervisor monitor your research progress?
   a. How does he/she you give you feedback on your progress? Do you ask for feedback from your supervisor?

8. How does your supervisor motivate you to do research?
   a. What are your barriers to conducting research (emotional, disinterested, personal problems, stressed over doing research)? How does your supervisor help you with these?

9. Does your supervisor prepare you for your research/ thesis exams?
   a. Do you know what the thesis examination format is like?

10. (For students beyond Year 4) Have you failed your research exams? How did your supervisor respond?

**Student-Supervisor Roles and Relationship**

5. Does your relationship with your supervisor change over time? Could you describe your relationship with your supervisor?

6. Do you think of clinical and research supervision differently? If yes, how?
   d. Do you switch roles between being a clinical supervisee and research student? If yes, how?
   e. Do you blend research and clinical supervision (e.g. clinical justification, recommendations for future research)?
   f. What would you say is your priority? Why do you say so?
      i. Do you think a research component is necessary for a clinical master’s program?

7. How do you feel about research supervision?
   a. Probe: Enjoyable or not? Meaningful or not? And why?
   b. How does your experience of research supervision compare to clinical supervision?

8. What benefits do you get out of this research supervision?

**Training for research supervisors**

4. Are you aware of any criteria or training for appointing research supervisors in your department?

5. What support do you need for your research component?
   a. Support from supervisors
   b. Support for students
Pharmacist-structured review of proton pump inhibitor utilisation in primary care: A non-randomised control study

Su Li Wong, Norharlina binti Sulaiman, Kar Mun Ng, Zhe Yen Lee


Abstract

Introduction: In the primary care setting, proton pump inhibitor (PPI) overutilisation often stems from the failure to discontinue prophylaxis treatment prior to tertiary care discharge and consider step-down therapy following discharge. Long-term PPI use can result in potential drug-related problems and unnecessary drug expenditure. This study aimed to evaluate the effectiveness of pharmacist-structured review in reducing inappropriate PPI prescriptions and estimate the potential cost saving.

Methods: This non-randomised controlled study was conducted for 16 weeks at 17 government health clinics in Selangor, Malaysia. Eligible patients attending the outpatient pharmacies of intervention clinics were recruited consecutively and their consent was obtained. A structured review of PPIs was performed in which pharmacists identified patient demographics, indications and the length of PPI therapy using a PPI intervention form. Recommendations were discussed with physicians before prescription changes were made and documented. Moreover, standard management was conducted in the control clinics.

Results: A total of 568 patients with prescriptions containing PPIs were sampled, with a total of 284 patients being placed into the control and intervention groups, respectively. Compared to the control group, inappropriate PPI utilisation in the intervention group significantly decreased from 79.9 to 30.4% (p<0.05). The changes to PPI prescriptions observed in the intervention group included: stop PPI therapy (30.8%), step-down therapy (22.9%), start substitution therapy (15.9%) and no change (30.4%). The physicians’ acceptance rate for pharmacist intervention was 67.8%. A 66.1% reduction in monthly PPI pill count and a 72.0% reduction in monthly medication expenditure (RM44.85/patient/year) were observed.

Conclusion: The pharmacist-structured review was effective in increasing appropriate PPI utilisation and led to substantial cost savings.

Introduction

Proton pump inhibitors (PPIs) suppress gastric acid secretion and effectively treat acid-related gastrointestinal disorders such as hypersecretory conditions, duodenal ulcers, gastric ulcers, gastroesophageal reflux disease (GERD), heartburn, upper gastrointestinal bleeding and Zollinger-Ellison syndrome, whilst also being useful in Helicobacter pylori eradication as well as stress ulcer- and drug-induced peptic ulcer prophylaxis. Their effectiveness has contributed to the overuse of PPIs, which has become a growing global concern. The overutilisation of PPIs in the ambulatory care setting often stems from the failure of the hospital to discontinue prophylaxis treatment before discharge, re-evaluate PPI therapy and consider on-demand and step-down therapy following discharge.

Numerous studies have emerged with reports on the overutilisation of PPIs, claiming up to 68% inappropriate PPI indication among hospital inpatients in developed countries. An observational study conducted in 31 primary care settings in Germany found that 58% of patients were discharged from hospital without any clear indication of PPIs; however, PPIs were continued by primary care physicians for at least 1 month thereafter. Notably, inappropriate long-term PPI use can lead to poorer clinical outcomes. Patients who are on long-term PPI therapy are more susceptible to variations in the bioavailability of common medications, vitamin B12 deficiency, Clostridium difficile infections, community-acquired pneumonia as well as hip, wrist and spine fractures.
Patients who were prescribed long-term PPI use should be regularly reviewed to assess the need for continuation.\(^9\) Canadian Consensus Guidelines and Australian National Prescribing Guidelines recommend that PPIs should be discontinued after 4–8 weeks of initial treatment unless indicated for long-term treatment. If symptoms recur, the reintroduction of PPIs at the lowest dose and frequency necessary to control symptoms is recommended.\(^9,10\) Although treatment algorithms are useful for day-to-day practice, a systematic review recommended that the dosage and duration of a PPI treatment should be individualised to each patient’s condition and setting.\(^11\) Notably, medication review has been useful in optimising patient medication utilisation especially for those with chronic conditions.\(^12\) In primary care, a pharmacist-led medication review is an essential strategy that enables appropriate PPI use. Pharmacists can reduce the overuse of PPIs and their associated costs in primary care by conducting a standardised, guided intervention.\(^13-15\)

Studies performed in hospitals within the states of Sarawak, Pahang and Selangor reported that 58.1, 31 and 46% of inpatients on PPI acid suppression treatment did not have appropriate indications, respectively.\(^3,16,17\) However, issues of PPI continuation and treatment review have not been comprehensively explored among primary care clinics in Malaysia. The overutilisation of PPIs in our healthcare setting has raised clinical and financial concerns among pharmacists. An average PPI usage of 17 months was observed, with an expenditure of RM91.36/patient/year.

Our study aimed to evaluate the effectiveness of pharmacist intervention on long-term PPI use by comparing the differences in appropriate prescribing and cost savings between the intervention and control groups.

**Methods**

**Study Design and Setting**

This was a multi-centre, non-randomised controlled study on the effectiveness of the pharmacist-structured review of PPI prescriptions in primary care. The study was conducted in 17 government primary healthcare clinics located in two different districts in Selangor State. These districts were purposely selected due to their comparable population numbers and sociodemographics.\(^18\) Nine clinics in the same district were chosen as intervention sites where the pharmacist-structured review of inappropriate PPI use was initiated by the district’s standardised clinical management. The remaining eight clinics under the second district were assigned as control sites that had no such review.

Choosing clinics under the same district as control groups would ensure that the patients were naïve to the intervention and any inappropriate PPI use was solely intervened via typical practice. A total of three clinics with no resident pharmacist were excluded from the study since the review of prescriptions by pharmacists was not possible. Another three clinics with no computerised prescription records were also excluded. Data collection was conducted for a 6-month period from November 2017 to April 2018.

**Sample Size Estimation**

The total population was estimated based on the PPI prescription records generated by the computerised dispensing systems (i.e., Pharmacy Information System (PhIS) and Tele-Primary Care System (TPC)) implemented by all the clinics since 2015. Based on a previous study by Oh et al., the sample size was computed using the Two-Proportion Sample Size Calculation in EpiCalc2000 with 99% CI, whilst an additional 10% accounted for loss. To represent the total population of patients using PPIs, the intervention and control groups required a minimum of 266 samples each.

**Participants**

In both intervention and control clinics, consecutive patients attending outpatient pharmacies within the study period were identified by pharmacists at the screening counters. Randomisation or systematic sampling was not feasible in our subject recruitment since patients’ attendance at the pharmacy counter was not predetermined. However, the control group was essentially equivalent to the intervention group based on known pre-intervention characteristics, which would eliminate unknown biases.

The inclusion criteria for both groups were adult patients (above 18 years old) and present with any type of new PPI prescription or refill prescription. The exclusion criteria were currently on *Helicobacter pylori* eradication therapy, terminally ill, currently undergoing chemotherapy or radiotherapy, waiting for referral appointments at other healthcare facilities and requiring less than 8 weeks of treatment.
Additional exclusion criteria for patients in the intervention clinics were cognitive impairment, unable to communicate well and represented by another person to collect the medication.

**Study Instrument**

The pharmacist-structured review was conducted using a PPI intervention form (Appendix 1) in the intervention clinics. This form was adapted from National Prescribing Service Limited, Australia, 2009. The form was modified to suit our study objectives and evaluated before use by two senior pharmacists and one family medicine specialist (FMS) who were not otherwise involved in the study. The form and data collection workflow was piloted by involving eight respondents in one of the intervention clinics. Since the form was completed by trained pharmacists, there was no requirement for the content to be translated from English to other languages.

This form was used to extract the patient data, dose and indication of prescribed PPIs, length of PPI therapy and concurrently prescribed medication that may exacerbate gastrointestinal symptoms or interact with the PPIs. Patients’ responses about their current PPI dose consumption and concurrent self-medication were also captured. The form was also used to record pharmacists’ recommendations based on their structured review as well as changes made to the PPI prescription following consultations with the doctors.

In the intervention clinics, the research team provided two series of central training for pharmacists on how to recruit respondents, extract data from the prescriptions and patient medical records and how to complete the PPI intervention form. For items that need responses from the subjects, the pharmacists were required to read out all of the answer choices. They were also given continuous pharmacy education (CPE) on the rational use of PPIs based on clinical guidelines by a clinical pharmacist to standardise their assessment of the appropriateness of PPI prescriptions. Training sessions were repeated by the trained pharmacists at individual clinics using a standardised training slide presentation. An in-house PPI counselling guideline and PPI patient information leaflet (PIL) were provided by the Clinical Pharmacy Unit and made available in the pharmacies of the intervention clinics.

**Intervention**

In the intervention clinics, pharmacists at the screening counter attached the patient information, consent form and PPI intervention form to each selected prescription. All eligible and consenting patients were interviewed and counselled at the pharmacy counter during medication dispensing by another pharmacist assigned to the dispensing counter. Structured reviews of PPI prescriptions were individualised and guided step by step as the pharmacists completed the information required in the PPI intervention form.

For patients with inappropriate PPIs and those who were non-compliant to PPIs and symptom-free, pharmacists made recommendations to either reduce the dose, change PPI use to an as-needed basis (PRN) or every other day (EOD) dosing, or stop PPI with or without H2-antagonist therapy initiation. Pharmacists’ interventions and recommendations were communicated to the physicians via telephone calls. Changes in the medication regime were made upon the physicians’ agreement and recorded. Since pharmacists’ review notes were attached to patients’ clinic appointment cards, the intervention will be noted during subsequent clinic visits.

Counselling on the changes agreed upon by physicians regarding the PPI regime, utilisation of H2-antagonist therapy or antacids on a PRN basis, and lifestyle changes was provided to patients during medication dispensing. PILs were disseminated to the patients at this point. For patients with appropriate PPI use, counselling on medication adherence, drug-drug interaction, the monitoring of adverse reactions and alarm symptoms was given.

In the control clinics, no structured review, prescription intervention or counselling on PPIs were performed.

**Data Collection**

Data for the intervention group was extracted from the completed PPI intervention forms from all clinics by two researchers. Agreement on data interpretation from both researchers was maintained. For the control group, data were extracted from prescriptions as well as patient medical and supply records. In both groups, the PPI regime for each patient was captured at baseline and the changes in subsequent prescriptions were traced via the computerised prescription record 16 weeks after the initial recruitment.
Patients’ PPI indication and duration of therapy were two important parameters in evaluating its appropriateness. For both groups, PPI indication had to be identified from patients’ medical records or referral letters if it was unavailable from the prescriptions. To identify the treatment duration, the PPI start date was taken from the discharge date stated in the referral letter from hospitals. If the PPIs were started in the health clinics, the date of the first prescription was considered the PPI start date.

Outcome Measurement
There were three main outcome measures in the intervention and control clinics: 1) the rate of inappropriate PPI prescriptions (analysed using descriptive analyses); 2) therapy changes 16 weeks after initial recruitment; 3) potential medication cost savings in terms of the pill count per month and average cost per month of PPI usage. According to the Canadian Family Physicians Evidence-based Clinical Practice Guideline on Deprescribing PPI 2017, inappropriate PPI utilisation is defined as unclear, unknown and undocumented indication and duration of treatment.11 PPI treatments initiated for a short course of 4–8 weeks are regarded as long-term treatment if the duration extends beyond 8 weeks. For the first outcome, PPI prescriptions were classified as inappropriate when their utilisation was not indicated for long-term treatment in accordance with this guideline.

Data Analyses
Data analysis was performed using the Statistical Package for Social Science (SPSS) version 21 and Microsoft Excel 2011. All descriptive analyses were reported in frequencies, means and standard deviations with 95% confidence intervals. Comparative analyses were conducted using the appropriate binomial test, t-test or chi-squared test since the age, treatment regime and duration of PPI treatment in control and intervention groups were normally distributed. Confidence levels were set at 95% and a p-value of <0.05 was regarded as statistically significant.

Ethical Considerations
This study was registered under the National Medical Research Register (NMRR) with registration number NMRR-17-3097-37220, approved by the Malaysian Research Ethical Committee (MREC) and allowed by relevant local and national authorities. All patient details were treated as private and confidential and kept under the strict control of the researchers only.

Results
A total of 290 eligible patients were initially enrolled into the intervention and control groups, respectively. However, 6 patients were excluded (3 per group) due to the unavailability of subsequent prescriptions, resulting in a total of 284 patients per group.

Table 1. Baseline characteristics of the study population (N=568) of 17 primary care clinics.

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Control group (n=284)</th>
<th>Intervention group (n=284)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years) * (Mean±SD)</td>
<td>63.4±12.2</td>
<td>63.8±11.6</td>
<td>0.686</td>
</tr>
<tr>
<td>Gender**</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>153 (53.9)</td>
<td>155 (54.6)</td>
<td>0.917</td>
</tr>
<tr>
<td>Male</td>
<td>131 (46.1)</td>
<td>129 (45.4)</td>
<td></td>
</tr>
<tr>
<td>Race**</td>
<td></td>
<td></td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Malay</td>
<td>136 (47.9)</td>
<td>93 (32.7)</td>
<td></td>
</tr>
<tr>
<td>Chinese</td>
<td>76 (26.8)</td>
<td>79 (27.8)</td>
<td></td>
</tr>
<tr>
<td>Indian</td>
<td>66 (23.2)</td>
<td>108 (38.0)</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>6 (2.1)</td>
<td>4 (1.4)</td>
<td></td>
</tr>
<tr>
<td>Type of PPI**</td>
<td></td>
<td></td>
<td>0.103</td>
</tr>
<tr>
<td>Omeprazole</td>
<td>180 (63.3%)</td>
<td>234 (82.4%)</td>
<td></td>
</tr>
<tr>
<td>Esomeprazole</td>
<td>1 (0.7%)</td>
<td>8 (2.9%)</td>
<td></td>
</tr>
<tr>
<td>Pantoprazole</td>
<td>103 (36.3%)</td>
<td>42 (14.7%)</td>
<td></td>
</tr>
<tr>
<td>Frequency of PPI ** Twice daily (BD)</td>
<td></td>
<td></td>
<td>0.025</td>
</tr>
<tr>
<td>Once daily (OD)</td>
<td>5 (1.8%)</td>
<td>5 (1.6%)</td>
<td></td>
</tr>
<tr>
<td>Every other day (EOD)</td>
<td>273 (96.1%)</td>
<td>260 (91.5%)</td>
<td></td>
</tr>
<tr>
<td>When necessary (PRN)</td>
<td>1 (0.4%)</td>
<td>0 (0.0%)</td>
<td></td>
</tr>
<tr>
<td>Duration of PPI therapy*</td>
<td></td>
<td></td>
<td>0.003</td>
</tr>
<tr>
<td>*Mean±SD</td>
<td>14.1±11.5</td>
<td>16.9±11.1</td>
<td></td>
</tr>
<tr>
<td>*Range (month)</td>
<td>3–62</td>
<td>3–77</td>
<td></td>
</tr>
</tbody>
</table>

All values are reported as n(%) unless otherwise stated(*).

* Independent T-Test, t.
** Chi-square test for independence, x².
Most patients were Malay females with a mean age of 63 years. There were no statistically significant differences between the two groups with respect to mean age and gender distribution. However, both groups had different ethnic distributions. Although both groups have a similar PPI prescription trend in terms of PPI choice, no similarities were observed in PPI frequencies and treatment duration at baseline. Differences in PPI prescribing patterns were expected since the intervention and control clinics were under two different districts with different practices and prescribing preferences.

**Figure 1.** Flowchart describing the subject recruitment and study process.

**Table 2.** Clinical indications for PPI therapy.

<table>
<thead>
<tr>
<th>Clinical indication</th>
<th>Control group (n=284)</th>
<th>Intervention group (n=284)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>NOT indicated for long-term use (inappropriate PPI continuation)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>GERD/reflux/dyspepsia/heartburn</td>
<td>19 (6.7%)</td>
<td>83 (29.2%)</td>
</tr>
<tr>
<td>Mild to moderate oesophagitis</td>
<td>1 (0.4%)</td>
<td>8 (2.8%)</td>
</tr>
<tr>
<td>Peptic ulcers (including Non-steroidal anti-inflammatory drugs (NSAIDs) or <em>H. pylori</em>–induced ulcers)</td>
<td>7 (2.5%)</td>
<td>15 (5.3%)</td>
</tr>
<tr>
<td><em>H. pylori</em> eradication</td>
<td>1 (0.4%)</td>
<td>3 (1.0%)</td>
</tr>
<tr>
<td>Unknown</td>
<td>171 (60.2%)</td>
<td>105 (36.9%)</td>
</tr>
<tr>
<td>Other</td>
<td>26 (9.2%)</td>
<td>13 (4.6%)</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>225 (79.2%)</td>
<td>227 (79.9%)</td>
</tr>
</tbody>
</table>
Table 2 presents the clinical indications for PPI therapy in the study population. At baseline, similar numbers of patients with inappropriate PPI prescriptions were observed in both groups (n=227, 79.9% in the intervention group and n=225, 79.2% in the control group). In both groups, an unknown reason for the continuation of PPIs was observed in nearly half of the patients (n=276/568, 48.6%).

Primary Outcome: Rate of Inappropriate PPI Prescriptions
After the 16-week intervention period, 86 patients (30.3%) continued with PPI prescriptions. This represents a statistically significant reduction (p <0.05) of inappropriate PPI use with the intervention (Figure 2). In the control group, 219 patients (77.1%) continued with inappropriate PPI prescriptions and followed standard management at the care setting at the end of the study period.

Secondary Outcome: Therapy Changes
In the intervention group, pharmacist recommendations were made via phone calls to the physicians of 227 patients upon identification of inappropriate PPI usage. Changes were made to 198 prescriptions (Table 3), resulting in an 87.2% acceptance rate for pharmacist recommendations. In the control group, no changes were observed for most prescriptions.

Tertiary Outcome: Potential Medication Cost Saving
In the intervention group, a significant reduction (66.1%) in the monthly PPI pill count and a 72.0% reduction in monthly medication expenditure (RM44.85/patient/year) were observed.

Table 4. Monthly pill count and monthly pill cost saved after 16 weeks of intervention.

---

**Table 2**

<table>
<thead>
<tr>
<th>Clinical indication</th>
<th>Control group (n=284)</th>
<th>Intervention group (n=284)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indicated for long-term use</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prophylaxis of drug-induced dyspepsia/ulceration</td>
<td>59 (20.8 %)</td>
<td>54 (19.0 %)</td>
</tr>
<tr>
<td>Zollinger-Ellison syndrome</td>
<td>0 (0.0%)</td>
<td>2 (0.7%)</td>
</tr>
<tr>
<td>Barrett’s oesophagus</td>
<td>0 (0.0%)</td>
<td>0 (0.0%)</td>
</tr>
<tr>
<td>Severe oesophagitis</td>
<td>0 (0.0%)</td>
<td>1 (0.4%)</td>
</tr>
<tr>
<td>Strictures, scleroderma</td>
<td>0 (0.0%)</td>
<td>0 (0.0%)</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>59 (20.8%)</td>
<td>57 (20.0%)</td>
</tr>
</tbody>
</table>

---

**Figure 2.** Inappropriate PPI prescription reduction with and without pharmacist intervention. * p < 0.05, post-intervention, chi-squared test.
Other Drug-Related Problems

In the intervention group, patients’ PPI compliance was reported in the PPI intervention form, where pharmacists asked each patient how they currently take their PPIs. A total of 114 (40.1%) patients reported their non-compliance towards PPIs. Out of these patients, 35 (30.7%) were not taking them, 73 (64.0%) were taking them when necessary (PRN) and 6 (5.3%) were taking them on an EOD basis without any consultation with healthcare providers. This accounted for an estimated 4,755 unconsumed pills per month with an unused drug wastage of RM 8,156.85 per month.

This study identified four drug classes that can exacerbate or induce dyspepsia or ulceration that were taken concurrently with PPIs by 141 (49.6%) patients in the intervention group (see Figure 3). A total of 30 (10.6%) patients took medications that alter gastric pH (e.g., antacids and H2-antagonists) concurrently with PPI for their symptomatic control, which suggests the ineffectiveness of the PPIs they were taking. Physicians were notified of these cases for review during patients’ next appointment, where they may need to be seen by an FMS.

Figure 3. Concomitant use of medications that induce/exacerbate dyspepsia or ulceration.

Discussion

This study demonstrated that pharmacist-structured review effectively reduced the number of inappropriate PPI prescriptions whilst leading to therapy optimisation and substantial medication cost saving. Notably, drug-related problems (DRPs) related to medication non-compliance and drug-drug interaction can be concurrently addressed during such reviews.

Inappropriate PPI prescriptions were apparent in the majority (79%) of patients in public primary care clinics, while studies performed in Malaysian tertiary hospitals showed that 1 to 58% of the prophylactic PPIs prescribed were unnecessary. With pharmacist intervention, the appropriateness of PPI prescriptions was significantly improved by 49.5%, with the desired outcomes being on par with those of another similar study (53.1%) adopting a similar framework to increase the appropriate use of PPIs.

It was also observed that the rate of appropriate PPI use increased as the intervention period progressed, which suggests the need for greater awareness of this intervention as well as structured reviews of PPI use among pharmacists and physicians. The effectiveness of structured intervention tools for pharmacists was evident since there were no changes in the appropriateness of PPI use observed in the control clinics, with 77.1% of PPI users still having inappropriate PPI prescriptions at the end of the study period.

In both the intervention and control groups, 92.6% of PPI prescriptions were initiated by tertiary care hospitals. Patients were then referred to health clinics for the continuation

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of care. At baseline, patients had a mean PPI treatment duration of more than 1 year. These findings highlight the need for medication review following hospital discharge and raise concerns regarding potential side effects and higher health care costs.

In the context of this study, the continuation of PPI after hospital discharge may not be necessary since 4–8 weeks of PPI treatment had been completed through hospital inpatient and post-discharge outpatient prescriptions. Several studies have also shown that PPIs are often overused in the ambulatory care setting due to a lack of documented indications leading to the inappropriate and chronic use of PPIs.2,12

The pharmacists’ recommendations for PPIs therapy changes achieved an 87.2% acceptance rate from the physicians, which is consistent with the results reported in another study (89.4%).14 We did not enquire about the reasons for the remaining pharmacists’ recommendations not being accepted. However, based on pharmacists’ observations, physicians may have made their own clinical judgments based on the individual patient since PPI tapering down may not be suitable due to factors such as age, the seriousness of the disease or the unwillingness of the patient to changes in therapy. Therefore, pharmacist recommendations may not be the only factor causing physicians to change PPI therapies.19,20

Pharmacist intervention in PPI use profoundly contributed to reducing medication expenses by up to 72%. This was also observed in a previous study, which noted a 72.6% cost reduction.14 However, our study did not further investigate the costs incurred due to substitution therapy, treatment for rebound gastrointestinal symptoms and the re-initiation of PPIs. The cost of hospital admissions or referrals were also not investigated.

Pharmacist-structured reviews using a guided checklist may also highlight therapeutic issues such as drug-drug interaction, contraindication and non-compliance issues in patients. Highlighting these DRPs for physicians may further reduce the medication list, optimise the treatment of other underlying chronic diseases and improve patients’ medication compliance. Notably, this would require another study outlining the different objectives of this study.

The current clinical practice guideline available in Malaysia does not specifically mention the deprescribing of PPI therapy.20 In our setting, there is no standard practice for PPI deprescription, which may have limited physicians’ acceptance of pharmacists’ recommendations. This has led to our interest in embarking on a future collaboration with physicians and FMSs to implement a PPI deprescribing algorithm.

A multi-disciplinary approach to improving the appropriateness of PPIs utilisation can be advocated based on several published clinical guidelines.9,10,13 It is important to routinely review this group of patients to ensure clinical and financial benefits for the respective stakeholders. The implementation of a PPI deprescribing algorithm is highly recommended to standardise the management of patients who are newly discharged or newly initiated with PPIs.

Study Limitations

We experienced difficulties in obtaining complete patient medication histories and indications for PPI from the hospital referral letters in more than half of all subjects. This highlighted the importance of properly documenting referrals to primary care since confirmed diagnoses indicating long-term PPI use cannot be obtained via procedures or tests in a primary care setting.14

There was also a lack of information on how long the patients had been on PPI treatment and how long the treatment should be continued. As a result, the PPI start date was assumed to be the date of referral to the primary care level. Thus, therapy durations may be under-reported.

We did not follow the subjects after the intervention in PPI therapy to note any changes in patients’ clinical outcomes. Therefore, whether or not there was any reduction in the adverse effects of long-term PPI use remains unknown. It would be valuable for future studies to measure the reduction of associated incidences and clinical outcomes after deprescription. Moreover, this study did not consider whether the structured review potentially reduced the bioavailability of other concomitant medications that interact with PPIs.

Since this was a non-randomised controlled study, the results should be interpreted with caution since potential biases may have
affected the analyses. We suggest that it would be valuable for future studies to be conducted with the rigorous standards of a randomised clinical trial to provide a higher level of confidence in the results.

**Conclusion**
The inclusion of pharmacists in a structured medication review framework demonstrated significant impacts on PPI use when compared to current standard management without pharmacist involvement. This study shows that judicious prescribing and patient care can potentially lead to medication cost savings.

**Acknowledgements**
We would like to thank the Director-General of Health, Ministry of Health Malaysia for the study approval and National Medical Research Registration Identity (NMRR-17-3097-37220) required to conduct this study. We also thank Dr Goh Pik Pin from the National Clinical Research Centre (NCRC) for providing us with the time and resources necessary to work on the publication of this paper.

**How does this paper make a difference to general practice?**
- This paper highlights the effectiveness of a pharmacist-structured review in detecting and reducing the inappropriate use of proton pump inhibitors (PPIs).
- Inappropriate PPI use significantly decreased in the intervention group when compared to the control group.
- The pharmacist-structured review protocol implemented in this study can be replicated in other health care settings.
- This study provides baseline findings for future work in developing and implementing a PPI deprescribing algorithm in the primary care setting.

**References**


A mysterious clavicular swelling
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Keywords:
Clavicular metastasis, non-small cell lung carcinoma, clavicular mass, lung adenocarcinoma

Abstract
The clavicle or collarbone is a horizontal-axis bony structure located between the neck and thoracic area. Tumour metastasis at the clavicle is very rare. Due to its location at the border of the neck and chest area, a primary tumour could originate from both areas. We report the case of a 39-year-old man who presented with a painful right sternal-end clavicular mass and intermittent fever. Chest radiography was normal. Musculoskeletal ultrasound of the clavicle revealed a mass. Computed tomography (CT) thorax further identified a mass at the upper lobe of the right lung. CT-guided tissue biopsy confirmed that it was a lung adenocarcinoma. This case shows an atypical presentation of lung carcinoma and how musculoskeletal ultrasound helped in the diagnosis when other features and investigations were inconclusive.

Introduction
Clavicular swelling is most commonly due to trauma or non-union healing fractures. Inflammation and bone tumours are the other possible causes. There are few reported cases of tumours involving the clavicle, which account for only 0.45–1.01% of all bony tumours.1 Most of these clavicular tumours were malignant and composed of Ewing’s sarcoma, osteosarcoma and myeloma.3 Meanwhile, other differential diagnoses include osteomyelitis, tuberculosis and infection at the sternoclavicular joint area. However, lung carcinoma with clavicular metastasis has never been reported despite the proximity of both structures.

Case history
A 39-year-old man presented to the emergency department with a complaint of pain and progressively enlarged right medial clavicular swelling with intermittent fever over a 4-month duration. He had no recent trauma, fall or traditional massage. He also had no cough, dyspnoea, haemoptysis, loss of weight, dysphagia, odynophagia or noisy breathing. He was an active smoker of 25 pack-years. Since he was a construction worker, he was constantly exposed to cement and concrete dust. There was no history of head or neck radiation, contact with tuberculosis patients or malignancy in his family. Although he previously sought treatment at multiple clinics and was given a few courses of oral analgesics and antibiotics, the pain and swelling were not reducing.

On examination, there was a firm-to-hard swelling at the right medial part of the clavicle measuring 3 x 3 cm. It was immobile and mildly tender on palpation. The overlying skin was normal. There were no palpable neck nodes. Bilateral upper limb neurological findings were normal. On the chest and clavicle radiographs, the right clavicle had a heterogeneously thickened medial end that was suspicious of a soft tissue lesion or lymph node (Figure 1). The lungs and remaining bones appeared normal. Tuberculosis workup (tuberculin skin test and sputum for acid-fast bacilli) were negative. Serum calcium level was normal. He was covered with intravenous augmentin (1.2 g) thrice a day for one week whilst admitted. However, the swelling and pain were not reducing. The patient’s poor response to medical therapy raised the suspicion of malignancy.

Ultrasound of the right sternoclavicular joint was performed to determine the origin and extent of the mass. It revealed a well-defined hypoechoic lesion with cortical destruction at the medial end of the right clavicle, thus raising the suspicion of a tumour or bony metastasis. Computed tomography (CT) neck and thorax showed a spiculated right apical lung mass measuring 4.1 x 3.4 x 5 cm (Figure 2). There were also bilateral supraclavicular and mediastinal lymph node enlargements, a right adrenal lesion and lytic lesions of the posterior part of the second right rib that were suggestive of distant metastases. CT-guided biopsy of the right apical mass identified it as primary lung adenocarcinoma. Our patient was diagnosed...
with lung adenocarcinoma (stage T1cN3M1). Epidermal growth factor receptor (EGFR) mutations were negative. The clavicular swelling and pain resolved after two courses of platinum-based chemotherapy.

**Figure 1.** A clavicular radiography study showed an irregular margin of the medial end of the right clavicle when compared to the medial end of the left clavicle (red arrow).

**Figure 2.** Ultrasound images of the bilateral medial end of the clavicle with enlargement of the right clavicle (A). The lesion is hypoechoic with bony cortical destruction (B).

**Figure 3.** A computed tomography image showing a lytic lesion with an erosion of the bony cortex of the sternal end of the right clavicle (red asterisk, axial view) and a small right apex of lung lesion measuring 1.19 x 2.56 cm (red arrow, coronal view).

**Discussion**

Trachea, bronchus and lung carcinoma is the second most common group of cancer among males and the fifth most common among females in Malaysia. Lung adenocarcinoma is the most common lung malignancy and strongly associated with smoking. A study by Noor et al. showed that chronic exposure to cement dust increased the risk for lung, laryngeal and gastrointestinal cancer as well as dermatitis. Our patient was at risk for lung cancer since he was an active smoker and worked in the construction sector, whereby he was constantly exposed to cement and concrete dust.

It is very rare for lung malignancy cases to present with a painful clavicular mass without any respiratory or constitutional symptoms. It is also rare for lung carcinoma to invade the clavicles since it is more commonly found to metastasise to the vertebrae, pelvis, humerus...
and femur. Clavicles are long flat bones that have no bone marrow.\textsuperscript{1} Cancer tends to spread to long medullary bones since there is more blood supply and the bone marrow provides a fertile microenvironment for the metastatic cancer cells to flourish.\textsuperscript{6} In our case, the tumour had most likely spread haematogenously since there was no direct extension from the right apical lung mass to the clavicle based on the CT images.

The clavicular swelling was hard in consistency with no egg-shell crackling sensation on palpation. Egg-shell crackling is a crepitus sensation during the palpation of a bony mass due to thinning of the bony cortex by the tumour mass. The likely reason for this is that the erosion of the bony cortex was at the medial side of the bone, which is a limited area for assessment. A radiography study is an easily available investigation that can be used to assess bony abnormalities. It has high specificity in detecting lesion features, which may help in determining the locations of lesions and their biological activity.\textsuperscript{7} However, it has a limited ability to visualise lesions near complex structures (e.g. ribs, the sternum, vertebrae), which require other modalities such as CT or Magnetic Resonance Imaging (MRI). In our case, a sternoclavicular joint ultrasound was able to detect the lytic lesion at the medial part of the sternal-end clavicle that was difficult to interpret in the radiography study. The lung mass was also obscured by the bony shadow.

The clavicle is a subcutaneously located bone. Thus, any lumps should be detected early. Despite its superficial location, tissue biopsy methods must be chosen wisely, especially at the medial part of the clavicle due to close proximity to vital structures such as blood vessels, nerve bundles, lungs and the trachea. A needle biopsy poses the risk of injuring the adjacent neurovascular structure and causing pneumothorax.\textsuperscript{1} There is also a risk of pathological fracture since bone consistency can be softened due to tumour erosion. Thus, hard manipulation during core biopsy should also be avoided. An open biopsy provides a surgical view that helps in targeting the tissue, acquiring a larger sample and avoiding injuries to nearby vital structures. The chosen biopsy method should strike a balance between the highest yield of tissue and minimising procedural complications. Fortunately, in our case, a CT-guided tissue biopsy of the lung mass was able to achieve the tissue diagnosis, thus avoiding the aforementioned complications of bone biopsy.

**Conclusion**

Persistent bone pain and swelling that do not respond to medical treatment should raise suspicions of malignancy. Non-traumatic painful clavicular swelling is rare and a high degree of suspicion is required for early diagnosis and treatment. Moreover, multidisciplinary team management is required with the integration of clinical, radiological and pathological inputs for a definite diagnosis, especially in such rare cases.

**Acknowledgement**

We would like to thank the patient who gave us permission for the publication of this case report. Moreover, we also thank all of the teams involved in treating this patient.

**Conflicts of interest**

All authors declare no conflicts of interest.

**Patient’s consent for the use of images and content for publication**

Verbal consent obtained from the patient for the use of images and his case for the publication of this case report.

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**What is the implication to patients?**

The awareness of the potential of clavicular metastasis in lung malignancy by the health care professionals is important, as it can cause a delay in early referral to the tertiary centre for appropriate investigations to establish the definitive diagnosis and subsequently delay in initiating treatment.
References


CASE REPORT

Erythematous plaques of the vulvo-perineal region

Qin Jian Low, Tzyy Huei Lim, Shu Ann Hon, Seng Wee Cheo, Noranizah Wagino, Evelyn Wen Lee Yap


Abstract

Skin conditions are a common reason for consulting primary health care. The public frequently expects their primary health care providers to be able to recognise and treat common skin conditions with confidence. Primary care providers must be able to identify ‘red flag’ skin conditions that require dermatology referral. However, diagnosis is often delayed due to the non-specific clinical presentation, low incidence, slow evolution and long-term history of such lesions. We report the case of a patient with extramammary Paget’s disease that presented to her primary care provider and subsequently underwent a wide local excision.

Introduction

Extramammary Paget’s disease (EMPD) can initially present with chronic eczema-like skin changes around the genital region in both genders. EMPD is a rare condition with only a few hundred cases reported worldwide. However, the exact incidence remains unknown. EMPD represents approximately 6% of all cutaneous Paget’s disease cases and predominantly affects patients between the ages of 60 and 80 years, with a peak age of 65 years. It often affects areas where the apocrine sweat glands are abundant. These can occur around the vulva, perianal region, scrotum, penis or axilla. Frequently, females between the ages of 50 and 60 years are affected and some of the patients may have an underlying malignancy. It is important for primary care providers to identify this classical skin condition early and promptly refer affected patients to a dermatologist for a skin biopsy. The management of EMPD includes surgery and topical therapy. Prognosis depends on the early diagnosis and stage of the disease.

Case presentation

An 80-year-old woman experienced bilateral pruritic excoriation over her vulva region over a 2-year period. Her underlying comorbidities included hypertension, type II diabetes mellitus and dyslipidaemia. She was initially treated as having vulval candidiasis by her primary care doctor; however, the ‘rash’ did not improve with the topical therapy prescribed. Local examination revealed an extensive well-demarcated erythematous plaque over her bilateral labia majora extending to her buttocks (Figure A-B). The lesion was confined to her vulval skin. Per-vaginal speculum examination was normal. There was no inguinal lymphadenopathy or abdominal mass. Skin biopsy was consistent with EMPD involving her vulva (Figure C-G). She was also screened for synchronous cancer. Her mammogram, pap smear, colonoscopy, cystoscopy and abdominal scans were all unremarkable. She was subsequently referred to the plastic surgery team for a wide local excision of the lesion.

Discussion

EMPD is an uncommon intraepithelial adenocarcinoma that can affect the anogenital or axillae skin. The most commonly affected age group is the elderly (over 50 years old). There are two forms of Paget’s disease. Primary EMPD of the skin originates from the cutaneous layer, whilst secondary EMPD is associated with adenocarcinoma. Although the aetiology of EMPD remains unclear, the apocrine-rich glands of the skin are commonly involved. The vulva is the most commonly affected site, reported in 65% of all cases. Immunohistochemistry can be used to differentiate between primary and secondary EMPD. Cytokeratin 20 will be positive in secondary EMPD but negative in primary EMPD. On the other hand, GCDFP-15 will be positive in primary EMPD but negative in secondary EMPD. GCDFP-15 staining was not performed since the stain was not available.

Keywords:
Melkersson-rosenthal syndrome, orofacial granulomatosis, neurocutaneous disorder
CASE REPORT

Figure A-B. Well demarcated erythematous plaques seen over the vulval and perianal region.

Figure C. Extramammary Paget’s disease (H+E staining x100). Large, pale malignant cells arranged in clusters and single cells throughout the epidermis. There was no dermal infiltration.

Figure D. (H+E staining x200). Large tumour cells with pleomorphic, oval-shaped vesicular nuclei and abundant pale cytoplasm (white arrows).

Figure E. Paget’s cells intensely positive for carcinoembryonic (CEA) antigen.

Figure F. Cytokeratin 7 (CK7) demonstrates the immunoreactivity of tumour cells.

Figure G. Negative cytokeratin 20 (CK 20) immunoreactivity.

Pruritus is commonly reported among patients with vulval Paget’s disease, with some potentially experiencing excoriations and lichenification.1 Other reported symptoms include burning pain, irritation and weepy erosions. Due to the persistent pruritic eczematous lesions, many patients have been treated with a course of anti-eczema therapy. The possibility of synchronous malignancies should be considered since approximately 30% of these patients have a non-contiguous carcinoma (e.g., involving the breast, rectum, bladder, urethra, cervix or ovaries).

The standard treatment for EMPD includes wide local excision and Mohs micrographic surgery.3 Mohs micrographic surgery results in a lower relapse rate when compared to wide local excision. In cases where Paget cells have extended into the reticular dermis or are observed within lymphatics, a sentinel lymph node biopsy is required to decide on the extent of surgery.4 In non-surgical candidates, imiquimod cream can be used. In selected cases, radiotherapy may be attempted after a multidisciplinary team discussion. Generally, the 5-year overall survival rate is 75–95%. Although
Paget’s disease is often intraepithelial, it can progress to the invasive stage with distant metastases in some cases. The diagnosis of EMPD often triggers an extensive age-specific malignancy screening. Patients with EMPD need to have a long-term follow-up since they can develop recurrence.5

**Conclusion**

Primary care providers should be familiar with the presentation of EMPD and begin a detailed systemic and physical examination to look for any undiagnosed malignancy. Early referral to a dermatologist would be imperative for any patient with chronic non-resolving skin lesions in the anogenital region. Primary care providers must be aware of this rare skin disease (rather than familiar with it) and refer any patient with a non-resolving skin lesion early to rule out malignancy.

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**Informed consent**

Written informed consent for this paper (including images, case history and data) were obtained from the patient for the publication of this paper, including the accompanying figures.

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Yaws: The forgotten tropical skin disease

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Keywords:
Communicable disease, treponema pallidum, tropical disease, yaws

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Abstract

Yaws is a rare skin disease endemic to tropical countries caused by *Treponema pertenue*. It is highly infectious and spreads through physical contact. In Malaysia, it was presumably eradicated during the 1960s, with the last reported case published in 1985. Due to its rarity, the disease often goes unrecognised and misdiagnosed. Here, we report the case of a 5-year-old aboriginal boy diagnosed with secondary yaws who presented with fever and an incidental finding of chronic painless ulcerated nodules and plaques on his lower limbs and gluteal region. His diagnosis was confirmed serologically with a venereal disease research laboratory lab test and he was successfully treated with a single dose of intramuscular benzathine penicillin G. Primary care physicians should not ignore this disease since its early recognition and appropriate treatment is vital to its eradication, especially in high-risk communities.

Introduction

Yaws, or *Framboesia tropica*, is a long-forgotten tropical skin infection caused by a highly infectious gram-negative spiral-shaped bacterium known as *Treponema pallidum pertenue*.1–6 It spreads via direct skin-to-skin contact with an infected lesion and is most prevalent in children between the ages of 2 and 15 years old. Boys are reportedly more prone to infection because they are physically active and more likely to acquire abrasions in the lower limbs.2–3 It is also known as a poor man’s disease because it mainly affects populations living in the isolated and rural areas of tropical countries, where the climate is warm and humid.3 Yaws is frequently missed due to healthcare providers’ inexperience. It is diagnosed clinically and requires serological confirmation.5–7 The fact that it spreads through physical contact makes it highly contagious, especially among family members. Treating patients whilst also administering prophylaxis and contact screening household members is of great importance.

Case Report

A 5-year-old boy of aboriginal descent from the ‘Batek’ tribe presented to the district hospital with a one-day history of fever, lethargy and pallor. The initial investigation showed haemoglobin of 3.9 mg/dL, an eosinophil count of 2.3% and a total white blood cell (TWC) of 11.3 cells 10^9L. He was then admitted for further workup. During admission, his mother reported skin lesions on his lower limbs that worsened over four months. The lesions began as a small, solid, rounded skin bump on his left ankle, which became larger, more prominent and subsequently produced yellow discharge. As the weeks progressed, similar lesions appeared on his buttocks and thighs. He denied any pain from these lesions or at any joints.

On physical examination, he was alert and conscious but pale. His temperature was 37.8°C. There was a yellow-crusted, ulcerated nodule on his left ankle (Figure 1) and multiple granulomatous plaques on his buttocks and thighs (Figure 2). The nodule was non-tender but exuded a yellow discharge. His other vital signs and systems examinations were unremarkable.

Figure 1: Nodule with yellow crust on the patient’s left ankle shows the ‘mother yaw’.

Figure 2: Granulomatous plaques on the patient’s buttocks and thighs.

Case Report

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Figure 1: Nodule with yellow crust on the patient’s left ankle shows the ‘mother yaw’.

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He was initially treated for a bacterial skin infection due to documented fever on admission and was started on syrup cloxacillin and KMNO4 dressing. He was also transfused with two pints of packed cells. He underwent a Mantoux test for tuberculosis and serological tests for *Treponema* to rule out possible causes of the tropical skin infection. Only the *Treponema pallidum* hemagglutination (TPHA) test and the rapid plasma reagent (RPR) came back as positive with a high titre of 1:256. His haematology workup showed features of iron deficiency anaemia, whilst other biochemistry investigations were unremarkable.

A senior dermatologist then diagnosed his skin lesions as yaws based on the clinical and serological findings. The patient received a single dose of 1.2 million units (MU) of intramuscular benzathine penicillin G and cloxacillin was stopped. At his 1-week follow-up, his lesions appeared as hypopigmented scarring with no residual plaques (Figure 3).

His immediate household contacts (including neighbours) were asymptomatic. However, they were screened serologically through a venereal disease research laboratory (VDRL) and given an empirical treatment with a single oral azithromycin dose of 30 mg/kg for children and 2 g for adults.

**Discussion**

In Malaysia, the earliest recorded campaign against yaws was carried out by Viswaligam in 1920, who treated cases of yaws in four states—Negeri Sembilan, Pahang, Perak and Selangor. At that time, the median number of cases reported annually was over 12,200.\(^5\) In 1954, with the assistance of the World Health Organization, a yaws elimination unit was established in the Ministry of Health and was thought to be successful.\(^5\) However, sporadic cases reappeared in the 1970s and the last available reports were published in 1989.\(^2,7,9\)

Yaws occur mostly in children and thrives in humid, tropical regions, causing ulcers on the thin skin covering bones.\(^3,5\) Clinically, yaws is divided into primary, secondary and tertiary phases. The primary lesion, known as the ‘mother yaw’, usually appears on the lower extremities as a localised painless papule that progresses into an ulcerated nodule (as seen in our case). It takes weeks to years after the primary infection occurs for secondary lesions to appear.\(^6,8\) Secondary lesions are the result of the lymphatic and hematogenous spread of the organisms and can present as a solitary papillomatous nodule, an ulcer or develop as multiple scaly discoid plaques with or without bone pain.\(^6,9\) If left untreated, bone deformity and destruction can manifest as late or tertiary...
yaws, usually 5–10 years after inoculation. In 65–85% of reported cases, the primary lesion is found on the legs and ankles and may spontaneously heal after 3 to 6 months. Our patient’s skin manifestation appeared 4 months after the initial lesion on his ankle, which matches the description of secondary yaws without arthralgia.

The diagnosis is straightforward in known endemic communities but increasingly challenging in countries like Malaysia, which lacks experienced medical personnel and active community health programmes to educate and identify yaws. Differential diagnosis is extensive and includes other tropical diseases such as mycobacterial disease, cutaneous leishmaniasis and fungal infections. Since primary healthcare providers can be unfamiliar with the disease and its diverse clinical presentation, cases of yaws are likely under-reported or misdiagnosed. Our patient was initially treated for a cutaneous bacterial skin infection due to his presentation of clinical symptoms of fever and sociodemographic background as an aboriginal child.

Similar serological tests can be used to diagnose both yaws and syphilis. The non-treponemal agglutination tests (RPR and VDRL) show a positive result in untreated cases and can be used as a cure test because they usually revert to negative after successful treatment. The TPHA and Treponema pallidum particle agglutination assay are more specific but remain positive for life, even after successful treatment. The inability to serologically differentiate yaws and syphilis can be an issue where the prevalence of syphilis is high. Yaws is still endemic because the existing serological tests cannot distinguish between them and patients are likely treated as having syphilis.

Since the 1940s, the mainstay treatment for primary and secondary yaws involves a single dose of 2.4 MU of intramuscular benzathine penicillin G (for adults) and 1.2 MU for children under 10 years old. A single oral dose of azithromycin (30 mg/kg single dose; maximum dose 2 g) is also effective. However, in a meta-analysis of antibiotic treatments for trachoma, 10–15% of patients had side effects (e.g., nausea and vomiting) after a single dose of azithromycin. Some patients with previous exposure to macrolides from other infections are also more likely to develop resistance. Our patient was given 1.2 MU intramuscular penicillin to reduce the risk of side effects and antibiotic resistance.

The cure rate of yaws was more than 90% and a successful outcome is measured by the improvement of skin lesions and a 4-fold reduction in the VDRL titre at least 1 year after the initial treatment. In this case, a skin biopsy was not performed since the mother did not consent to it. Also, a repeat titre was not performed later due to the patient defaulting on his subsequent appointments. In communities and endemic areas, a high suspicion for yaws should be propagated and attempts should be made to confirm the diagnosis serologically. Diagnosis of the specific Treponema species is necessary based on epidemiological data (children without a history of sexual relations and a VDRL-negative mother) since no histological, biochemical, immunologic or microbiological techniques can distinguish between Treponema species.

Conclusion
This case highlights a highly infectious tropical skin disease that was forgotten, which delayed appropriate treatment for our patient. This disease should be suspected in patients that fulfil the epidemiological and clinical criteria. Our physicians must be trained to identify the presentation and accurate management of yaws, especially those who work amongst impoverished communities in rural areas. Health education and mass screening for affected communities are crucial to teach them to remain alert for this disease and advocate for prompt treatment to eliminate it.

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Conflicts of Interest
No potential conflict of interest relevant to this article was reported.

Consent for Publication
As legal guardian to the child patient, the patient’s mother provided written and verbal informed consent for the publication of this case report.
How does this paper make a difference to general practice?

- A chronic painless papular skin lesion that grows into an exudative ulcer in a patient below the age of 15 should prompt general practitioners (GPs) to collect detailed medical history and perform serological VDRL tests to exclude yaws.
- GPs are usually the first point of contact for infectious diseases in endemic areas. To avoid possible clusters of infections in such communities, prophylactic treatment could be initiated by GPs using single-dose oral azithromycin.
- The eradication of this forgotten disease can be achieved if the symptoms and early signs of yaws can be recognised and treated comprehensively by GPs.

References

CASE REPORT

Distinguishing between isthmic thyroglossal duct cyst and goitre on nuclear thyroid scan: A case report

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Onimode YA, Ogunkeyede SA, Afolami P. Distinguishing between isthmic thyroglossal duct cyst and goitre on nuclear thyroid scan: A case report. Malays Fam Physician. 2021;16(3);108–111. https://doi.org/10.51866/cr1230

Abstract
Thyroglossal duct cysts, which are the most frequently encountered congenital cervical anomalies in children, occur due to embryologic remnants of the thyroglossal duct. Although diagnosis may be challenging, clinicians can be aided by imaging and fine-needle aspiration biopsies. We describe the clinical management of a two-year-old boy with a thyroglossal duct cyst mimicking a goitre on a pertechnetate thyroid scan.

Introduction
The thyroid gland develops between the fourth and eighth weeks of intrauterine life. The anlage descends from the foramen caecum at the base of the tongue, through the infra-hyoid visceral space and to the anterior neck. The thyroglossal duct connects the origin and final site of the anlage. This duct should involute at approximately the tenth week of life. However, it may persist as a thyroglossal duct cyst (TGDC).1

TGDCs are commonly encountered in children, with 50% of children presenting TGDCs in the first decade of life.2 TGDCs mostly present as a neck swelling that is mobile with tongue protrusion. It may also contain ectopic thyroid tissue (1.5–62%).3 Clinical features are important in making a diagnosis; however, imaging confirms the diagnosis, localises the thyroid gland and helps in decision making.4 Ultrasonography (USS) is an important initial imaging technique for TGDC, especially in children where radiation exposure must be minimal.5 Since 2006, pertechnetate thyroid scan (PTS) has been available at this facility and incorporated into clinical management. The latter is especially useful in localising thyroid ectopia. This article serves to illustrate the presentation and use of imaging studies to solve the diagnostic dilemma of a TGDC in the isthmus of the thyroid that simulated a goitre.

Case presentation
The patient was a two-year-old boy with asymptomatic, progressive midline anterior neck swelling referred for a PTS. He was referred from a secondary health facility due to the diagnostic dilemma in differentiating a suspected TGDC from an enlarged thyroid gland. The PTS scan aimed to determine whether this was the only thyroid gland in the patient since the cystic lesion was within the thyroid gland and the possibility to remove the entire diseased thyroid gland along with the cyst was high based on the preoperative assessment. Thus, the decision to search for ectopic and functional thyroid tissue is important before surgical care.

Figure 1. Anterior neck swelling observed at the patient’s presentation for the scan.

On clinical examination, the patient had an anterior midline neck mass that moved more prominently with deglution and not with tongue protrusion. It measured approximately...
2 x 1 cm, with no differential warmth or tenderness. The swelling was soft to firm, attached to underlying structures and the overlying skin appeared normal (Figure 1). Fine-needle aspiration cytology (FNAC) was suggestive of a benign lesion.

A PTS showed a focal area of increased uptake in the anterior neck corresponding to both the neck swelling and thyroid gland, thereby making the distinction between the TGDC and goitre difficult. Uptake was uniform but lower than that of the salivary glands and slightly higher than background activity. No evidence of ectopic thyroid tissue was observed in an expanded field of scan (head to abdomen), thus excluding the likelihood of ectopic thyroid tissue (Figure 2).

Subsequently, high-definition thyroid USS showed well-delineated normal thyroid tissue in the anatomical position as well as its size, outline and echogenicity along with a coexisting oval-shaped cystic mass of mixed intensity in the right para-median region. The cystic mass measured 14 x 10 x 15 mm, had a volume of 1.2 ml in the anterior neck, was attached to the thyroid isthmus and displaced the right thyroid lobe inferiorly, and was of normal colour flow Doppler interrogation, thereby confirming the potential for a TGDC.

Thereafter, the patient received a Sistrunk procedure. At surgery, there was an independent, tough, intact membrane containing serous fluid at the isthmus of the thyroid displacing the right lobe inferolaterally (Figure 3). It measured 24 x 2 mm and there were no enlarged lymph nodes in the surrounding tissues. The histological report confirmed a TGDC. The patient was discharged on the second postoperative day without any complications. At the follow-up clinic, a postoperative thyroid function test was within normal limits.

Discussion
In this case, the clinical presentation was that of an intra-thyroid benign cystic lesion with no cervical lymphadenopathy. Although TGDC is rarely associated with malignancy, papillary thyroid and squamous cell carcinoma have been reported in approximately 1% of patients with TGDCs. In this case, FNAC was suggestive of a benign lesion. In the management of TGDC, FNAC is reported as being safe and cost-effective in differentiating benign from malignant lesions.

In the process of making a correct diagnosis of suspected TGDC, one must ascertain the presence of the thyroid gland and ensure that the only thyroid tissue is not within the cyst to be removed. This would prevent one from unnecessarily subjecting a child to life-long thyroid hormone replacement therapy due to iatrogenic hypothyroidism. Radiological and nuclear thyroid imaging localise eutopic and ectopic thyroid tissue, thereby complementing each other in clinical diagnosis. In this case, PTS helped to detect viable thyroid glands and the TGDC. The subsequent distinction between the TGDC and goitre was difficult since the increased uptake on PTS corresponded to both visible neck swelling and the thyroid gland. Thus, differential diagnoses included ectopic thyroid, TGDC, or TGDC with viable thyroid tissue. The suboptimal uptake of radioactivity by the neck mass further supported the latter differential.
Clinical challenges experienced in the management of this patient were resolved by the complementary imaging of PTS and USS. Neck USS showed a complex relationship of the TGDC and adjacent normal thyroid tissue, which is responsible for the superimposition of focal cervical uptake on PTS. This arrangement explains the non-movement of the cyst with tongue protrusion. Although TGDCs are typically located in the infra-hyoid area, other presentations include intra-laryngeal extension, intra-lingual cyst and lateral neck swelling.  

In thyroid ectopia, the entirety or part of the thyroid gland may be located in unexpected sites other than the anterior neck, which is considered a form of thyroid dysgenesis. In this case, thyroid ectopia was excluded via additional nuclear imaging from the floor of the mouth to the supra-pubic region, with no ectopic thyroid being detected. The common locations of ectopia include the base of the tongue, trachea, submandibular, lateral neck and palatine tonsils, heart, thymus, oesophagus, stomach, duodenum, gallbladder and adrenals. 

Although isthmic TGDCs are rare, intra-thyroidal cysts have been reported. To our knowledge, this instance is an exceptionally rare case report of intra-thyroidal TGDC in Nigeria. In the present case, we did not find the thyroglossal duct tract. Nevertheless, the patient had an isthmeectomy and Sistrunk’s procedure to prevent the recurrence of the TGDC.

Conclusion

The clinical and radiological features of TGDCs are important for diagnosis. However, complementary imaging studies are essential for intra-thyroid TGDCs. This report adds to the published literature on cases of TGDCs.

Acknowledgements

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Conflicts of interest

The authors have no conflicts of interest to declare.

Patients’ consent for the use of images and content for publication

Patient’s caregiver provided written informed consent for use of images as well as consent for publication.

What is new in this case report compared to the previous literature?

- This case report provides additional evidence to the literature regarding intra-thyroid thyroglossal duct cysts.

What is the implication to patients?

Clinicians managing patients with a suspicion of thyroglossal duct cyst would keep in mind the possibility, though rare, of its being intrathyroid.

References


CASE REPORT

A rare cause of acute urinary retention in adolescents: A case of imperforate hymen

Erinna Mohamad Zon, Nik Rafiza Afendi, Nurul Bazilah Mansor, W Fadhлина W Adnan


Keywords: Imperforate hymen, haematometrocolpos, haematocolpos, acute urinary retention, adolescent

Abstract

Imperforate hymen is a genital outflow abnormality that can occur in females. It can present with various symptoms and is associated with short- and long-term complications that may affect patients’ quality of life. Acute urinary retention in adolescents is a rare occurrence. We report a case of delayed diagnosis of imperforate hymen involving multiple visits to the clinic for urinary symptoms and the subsequent development of acute urinary retention. Awareness of this rare presentation is essential since delayed diagnosis is associated with hydronephrosis, endometriosis and infertility in later life.

Introduction

Imperforate hymen is a genital outflow abnormality that can occur in females. It can present with various symptoms and is associated with short- and long-term complications that may affect patients’ quality of life. In adolescents, acute urinary retention is a rare occurrence and usually due to an obstructing pelvic or perineal mass. One of the differential diagnoses is colpomenorrhea due to the accumulation of menstrual blood above an imperforate hymen, which leads to distension of the vagina and stretching and lengthening of the urethra. The reason for discussing this case is to highlight clinical presentations and assessments that may help in diagnosing the condition in a primary care setting for early referral to a gynaecologist for intervention.

Case presentation

An 11-year-old girl presented to the accident and emergency department with a history of sudden onset acute urinary retention and suprapubic pain. She experienced difficulty in passing urine for the previous 2 months, which was associated with dysuria and incomplete voiding. She also complained of cyclical abdominal pain for the past 3 months. She had not yet attained menarche. There was no history of fever or vomiting. Her birth history and developmental history were unremarkable.

She had multiple visits to a private clinic for her symptoms, which were treated as a urinary tract infection (UTI). Although she had completed a few courses of antibiotics, her symptoms persisted.

On examination, she was alert, pink, afebrile and in pain. She was an appropriately built girl with the presence of well-developed secondary sexual characteristics. Her abdomen was soft with mild tenderness at the suprapubic area. There was a palpable mass at the suprapubic region, equivalent to a 16-week uterus size. Her bladder was also palpable. Perineal examination revealed a bulging imperforate hymen on Valsalva manoeuvre. Other systemic examinations were unremarkable. The bladder was catheterised and approximately 800 ml of urine was drained. Pelvic ultrasound revealed a distended uterus and vagina with homogenous and hyperechoic collection. A diagnosis of imperforate hymen with haematometrocolpos was made.

Figure 1. Left: Perineum examination noted imperforate hymen. Right: Ultrasound finding of a distended uterus with cystic collection in the vagina and a ground-glass appearance suggestive of blood collection.
Subsequently, the patient underwent a hymenectomy where a cruciate incision was made over the hymen. Approximately 300 ml of thick chocolate brown-coloured blood was drained.

Oral analgesics and antibiotics were prescribed post-operatively. The patient made an uneventful recovery and was well at the 1-month follow-up. She also started experiencing regular menses and had no further urinary problems.

**Discussion:**
Imperforate hymen is one of the most common obstructive lesions of the female genital tract. It is the result of failed embryologic canalisation of the most caudal portion of the vaginal plate at its juncture with the urogenital sinus. The incidence of imperforate hymen is 1 in 1000 to 1 in 2000 women.

It is rare to detect an imperforate hymen in infancy. Most cases of imperforate hymen are found at puberty. Around the age of menarche, an adolescent girl usually presents with amenorrhoea and cyclical abdominal or pelvic pain. Less common symptoms include back pain and constipation. If the accumulation of blood and cellular debris is large, it can compress the urethra and bladder, thereby giving rise to symptoms of urinary tract obstruction such as dysuria, urinary frequency and feelings of incomplete voiding. These symptoms can be mistaken as UTI symptoms, which explains why some patients are misdiagnosed as having a UTI. Delayed diagnosis will lead to acute urinary retention, as in the case of our patient. The incidence of acute urinary retention in patients with imperforate hymen is rare.

Assessing the history of pubertal development and examining secondary sexual characteristics are important in diagnosing adolescent girls. Menarche typically occurs within 2–3 years after thelarche (breast budding), at Tanner stage IV breast development. Imperforate hymen should be considered in all adolescent girls with breast development of at least Tanner stage III complaining of cyclical pelvic pain, back pain or urinary symptoms that have not attained menarche.

A simple clinical examination of the external genitalia usually reveals a tense, bluish bulging membrane that is pathognomonic of imperforate hymen.

A bedside pelvic ultrasound is sufficient to reveal blood collection in the vagina (haematocolpos) that may even extend to the uterus (haematometrocolpos) and (rarely) involve the fallopian tubes.

Early recognition and treatment of the problem are required to prevent long-term complications for endometriosis and infertility. Treatment of imperforate hymen involves the simple surgical procedure of hymenectomy.

**Conclusion**
Imperforate hymen is a diagnosis that can easily be made with a careful history, a complete examination and a high index of suspicion. Presentations of imperforate hymen vary from a classical presentation of amenorrhoea and cyclical abdominal pain or pelvic pain to symptoms of compression due to massive haematocolpos or haematometrocolpos collection resulting in symptoms of urinary retention, acute urinary retention, constipation or back pain. Symptoms of urinary retention mimic the symptoms of UTI; thus, these patients can be initially misdiagnosed as having a recurrent UTI. Early recognition of this condition will avoid complications such as acute urinary retention or endometriosis.

**Acknowledgements**
None.

**Conflicts of interest**
The authors declare that they have no conflicts of interest.

**Patient’s consent for the use of images and content for publication:**
Verbal and written consent obtained.
How does this paper make a difference to general practice?

- Cyclical abdominal pain in girls who had not yet attained their menarche is a classical symptom suggestive of outflow tract obstruction.
- Symptoms of recurrent UTI or acute urinary retention is a rare presentation of imperforate hymen.
- Knowledge of the pubertal stages is essential in detecting an atypical presentation of imperforate hymen, and an assessment of secondary sexual characteristics should be performed on all adolescent girls presented to the clinic with abdominal pain.
- Bedside ultrasound is important in the assessment of patients with pelvic/abdominal symptoms. This can be easily performed since most health clinics/GP practices are equipped with an ultrasound machine.

What is new in this case report compared to the previous literature?

Acute urinary retention in children is rare. Acute urinary retention presented due to imperforate hymen is even rarer. Although a few similar cases have been published before, many remain unaware of atypical presentations of imperforate hymen (e.g., acute urinary retention). The lack of awareness regarding atypical presentations of imperforate hymen must be addressed to prevent delayed or missed diagnoses leading to long-term complications.

What are the implications for patients?

The accumulation of blood in the vagina (and subsequently in the uterus) will cause cyclical pain for patients. The undiagnosed or delayed diagnosis of imperforate hymen causes unnecessary pain, which will disrupt patients’ studies and social interactions. It can also cause acute urinary retention (as in our case) due to compression of the urethra, which may lead to hydronephrosis.10,11 Furthermore, delayed diagnosis of imperforate hymen will increase the risk of menstrual blood backflow into the peritoneal cavity, which may increase the risk of endometriosis and infertility in later life.12

References

**CASE REPORT**

**Osteonecrosis as the presenting feature in a child with acute lymphoblastic leukaemia**

Sern Chin Lim, Bushra Johari, Swee Ping Tang


**Abstract**

A seven-year-old girl presented with pain in multiple joints and constitutional symptoms over a period of four months. There were no significant clinical findings apart from joint tenderness. Blood test results did not indicate any specific pathology and initial radiology imaging was normal. Subsequent careful examination of her X-ray images led to an MRI of her left knee, which revealed acute osteonecrotic changes. A following whole-body MRI examination demonstrated multifocal bony lesions. Bone marrow examination conclusively diagnosed acute lymphoblastic leukaemia (ALL). Acute osteonecrosis has classically been described as a complication of treatment in children with ALL and has not been recognised as a presenting feature until recently.

**Case Report**

A seven-year-old girl presented with complaints of pain in multiple joints for the past four months. She first developed pain over her right shoulder following a trivial fall. She was seen at an urgent care center and treated with an arm sling for a presumed hairline fracture of her right humeral neck. The pain gradually resolved and a subsequent X-ray two weeks later was reportedly normal. Later that week, however, she began complaining of pain in multiple joints, initially over the left shoulder and then over both knees. She also developed intermittent low-grade fever, and loss of appetite and weight. Her joint pains were intermittent, with no specific pattern.

A month later she presented to another hospital due to her complaints. Blood investigations showed a white cell count of 7.7 x 10^9/L, haemoglobin of 11 g/dL, platelets of 524 x 10^9/L, ESR of 17 mm/hr, C-reactive protein of 120 mg/L, lactate dehydrogenase of 556 IU/L, and negative anti-nuclear antibodies and rheumatoid factors. Peripheral blood films showed large, atypical lymphocytes with no blasts.

At presentation to our centre, the child was afebrile but had severe left knee pain with inability to ambulate. There was no swelling or erythema over her left knee, despite her being in severe pain with limitation of movement. Further systemic examination was normal. A provisional diagnosis of inflammatory arthritis with possible malignancy was made. Repeated blood investigations showed a white cell count of 7.7 x 10^9/L, haemoglobin of 11 g/dL, platelets of 524 x 10^9/L, ESR of 17 mm/hr, C-reactive protein of 120 mg/L, lactate dehydrogenase of 556 IU/L, and negative anti-nuclear antibodies and rheumatoid factors. Peripheral blood films showed large, atypical lymphocytes with no blasts.

A repeat X-ray of the left knee showed a suspicious appearance (Figure 1b). Following that, magnetic resonance imaging (MRI) of the left knee revealed multifocal lesions at the metaphysis and epiphysis of the distal femur and proximal tibia, exhibiting features consistent with osteonecrosis (Figure 2). Based on the MRI findings, a differential of acute leukaemia or chronic recurrent multifocal osteomyelitis was made. After a multidisciplinary discussion, a whole-body MRI was performed, which showed multiple lesions in the axial and appendicular bones (Figure 3). Subsequent bone marrow analysis was diagnostic of acute lymphoblastic leukaemia.
Figure 1. X-rays of seven-year-old girl with joint pain. (a) Initial X-ray (zoomed-in) of the left knee joint and the proximal tibia and fibula showed no significant findings. (b) A repeat X-ray three months later showed subtle lucency with surrounding sclerosis (arrow) at the proximal tibia.

Figure 2. MRI of the left knee of a seven-year-old girl with joint pain. T2 TIRM (29/5500) in sagittal section (a) showing geographical lesions at distal femur, with some areas exhibiting serpiginous double-line sign (arrows) of inner high-signal-intensity area, the reactive interface or zone of creeping substitution, and the outer low-signal-intensity sclerotic rim, favouring osteonecrosis. T1FS contrast-enhanced (14/726) coronal image (b) showed marginal enhancement of the lesions in the distal femur and proximal tibia.

Figure 3. Selected T2 TIRM images from MRI whole-body scan of seven-year-old girl with joint pain. Apart from the lesions around the left knee, more lesions were observed in the rest of the axial and appendicular skeleton. Shown here are the lesions in the (a) right femur (arrowheads), (b) left ischium (double arrows) and (c) thoracic vertebra (arrow).
Discussion
Acute lymphoblastic leukaemia (ALL) is the most common malignancy in childhood, accounting for approximately 30% of all childhood malignancies under the age 15 years and constituting nearly 80% of all childhood leukaemias. Acute leukaemia in children is known to present in myriad ways, ranging from non-specific constitutional symptoms to more concerning ones such as bleeding tendencies, generalised lymphadenopathy or hepatosplenomegaly.

Musculoskeletal manifestations in children with ALL are common and have been reported as the initial presentation in up to 30% of cases. Symptoms range from joint pains or swelling to more persistent bone pain. Often, clinical findings are non-specific and may be difficult to differentiate from inflammatory arthritis. The classical diurnal pattern of pain (inflammatory pain worse in the mornings and nocturnal pain in malignancy or infection) may sometimes not be obvious in young children, as evident in our patient. The four-month history of constitutional symptoms and absence of objective clinical findings of arthritis were uncharacteristic for inflammatory arthritis or other benign musculoskeletal conditions. Features that typically raise suspicion of malignancies like lymphadenopathy and organomegaly may not be consistently present and, indeed, were notably absent in our patient. It is therefore imperative to consider possible malignancies in children who present with persistent musculoskeletal complaints, especially if the presentation is atypical.

The most important initial test to diagnose acute leukaemia is a full blood picture, which typically demonstrates pancytopenia with the presence of blasts. This blood film may, however, be entirely normal in the early phases of the disease. Thus, a normal blood count, even in the absence of lymphadenopathy or organomegaly, should not exclude leukaemia if the clinical picture is suspicious. In such situations, a bone marrow examination is warranted.

Musculoskeletal radiographic abnormalities at diagnosis are well recognised in paediatric ALL, being reported in approximately 80% of cases in some series. The most common are metaphyseal lucencies (7.5 – 70%, according to published data). Other reported abnormalities include periosteal reactions, osteolytic lesions, osteopenia and pathological fractures from marrow infiltration. Osteonecrosis per se is not a generally known presenting feature of ALL and has only been recognised in recent literature.

Osteonecrosis varies in radiographic presentation depending on the stage, with normal radiographs in the earliest stages, progressing to subtle non-specific lucencies and collapse of the bone in the later stages. MRI remains the imaging modality of choice in the evaluation of osteonecrosis. The double-line sign of parallel hyper- and hypointense serpiginous lines representing reactive interfaces or zones of creeping substitution is considered diagnostic of osteonecrosis on MRI. Our case demonstrates the importance of not dismissing persistent musculoskeletal symptoms even when initial radiographs are normal.

Osteonecrosis in children has been classically described as a complication in the treatment of ALL. Incidence ranges from 1.8% to 8.9% in multiple studies; this is likely an underestimate, as many studies examined only symptomatic children. Prospective MRI studies performed in all ALL children, regardless of symptoms, quote a higher incidence 15.5% to 24%. The risk is higher in children older than 10 years with exposure to corticosteroids. The exact aetiology of osteonecrosis in children with ALL remains uncertain and the presence of early osteonecrosis in patients like ours who have not been exposed to corticosteroids or chemotherapy suggests that the inherent nature of ALL itself may play a role in the formation of these lesions.

Although MRI was very useful in our patient, clinicians should be mindful that MRI is not mandatory prior to a marrow examination. We would recommend a bone marrow examination in any child with a suspicion of a haematological malignancy, even without an MRI. Our case highlights the need for a thorough investigation in children with significant musculoskeletal symptoms despite scant clinical findings.

Ethics approval
This case report has been approved for publication by the Medical Research and Ethic Committee, National Institute of Health, Malaysia (NMRR-20-1414-55268)

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CASE REPORT

Conflicts of Interest
The authors declare that they have no conflicts of interest.

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How does this paper make a difference to general practice?

• Musculoskeletal manifestations in children with ALL are well known and can mimic arthritis or even osteomyelitis.
• Any persistent musculoskeletal symptoms, especially with atypical features such as constitutional symptoms or disproportionate pain, warrant a thorough investigation even if clinical findings are sparse.
• Plain radiographs may initially be normal in osteonecrosis and the presence of persistent and significant bone pain is an indication for more discriminatory tests, such as a CT scan or MRI.
• Absence of blasts on peripheral blood films does not exclude leukaemia, as these films may be normal in the early phase of acute leukaemia.

References


CASE REPORT

Alarming triad of progressive hoarseness in a male smoker

Nur Ain Nabila Za'im, Mawaddah Azman


**Keywords:** Hoarseness, laryngeal cancer, glottic carcinoma, smoker, red flags.

**Abstract**

Hoarseness accounts for 1% of all consultations in primary care. Suspicion of malignancy should be considered in individuals with risk factors presenting with unexplained hoarseness lasting more than two weeks. A significant number of patients with laryngeal cancer present at an advanced stage due to lack of awareness regarding vocal health. It is important to educate both the public and primary care health providers concerning laryngeal cancer. We present the case of an 81-year-old male smoker who presented to us with a six-month history of progressive hoarseness. He was initially treated in two primary and one secondary care centres, where a diagnosis of laryngeal cancer was not considered. Careful assessment in our centre managed to determine a diagnosis of T3N0M0 glottic carcinoma. We will discuss this alarming triad of progressive hoarseness in a male smoker to help primary care physicians streamline their thoughts and identify red flags in a hoarse patient.

**Introduction**

Hoarseness, or alteration of voice, accounts for 1% of all consultations in primary care. Its common causes are acute and chronic laryngitis, accounting for 42.1% and 9.7% respectively, followed by functional dysphonia, benign and malignant tumours, neurogenic factors and aging.1 Any patient complaining of persistent or progressive hoarseness lasting more than two weeks with risk factors should prompt immediate investigation and referral to a tertiary centre to exclude laryngeal cancer.2,3 Despite its early presentation with a striking symptom such as hoarseness, delayed referral to an otolaryngologist is commonly observed in laryngeal cancer, such as seen in our case.

**Case Presentation**

An 81-year-old Chinese male who was an active smoker was referred from a secondary centre with complaint of progressive hoarseness over the past six months, with no other associated symptoms. He visited two primary care clinics prior to his presentation, where two courses of antibiotics were prescribed over a period of two months. Subsequently, he was referred to a secondary centre where an otorhinolaryngology consult was obtained. Neck examination revealed a right anterior neck swelling, measuring 2x2cm, which moved with deglutition. Initial examination by the otolaryngologist at the secondary centre revealed left unilateral vocal fold paralysis with no suspicion of malignancy. A contrasted CT scan showed an enlarged left thyroid gland causing tracheal deviation (Figure 1). The patient was subsequently referred to an otolaryngologist at a tertiary centre for further management of a benign thyroid mass.

Endoscopic examination of the larynx at the tertiary centre showed left vocal fold immobility with an irregular mass on the left vocal fold (Figure 2). Histopathological examination of the left vocal cord and subglottic mass showed poorly differentiated squamous cell carcinoma. Fine needle aspiration cytological examination of the left thyroid lobe revealed benign follicular nodules. After further counselling, the patient underwent total laryngectomy, left hemithyroidectomy and left selective neck dissection (levels I, II and III) for T3N0M0 glottic cancer with left follicular thyroid nodule. Histopathological examination of the surgical specimen revealed squamous cell carcinoma with clear margins.

Keywords: Hoarseness, laryngeal cancer, glottic carcinoma, smoker, red flags.

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Figure 1. Axial cut contrast CT neck of an 81-year-old man with hoarseness showing a non-enhancing mass arising from the left vocal fold, which was missed by the secondary centre. A corresponding well-defined, non-enhancing thyroid nodule was seen arising from the right hemithyroid. In this instance, the initial finding of left vocal fold immobility did not correlate with a thyroid pathology.

Figure 2. Endoscopic images of the vocal cords of an 81-year-old man with hoarseness showing a fungating and friable mass arising from the left true cord (A: blue arrow) extending to the anterior commissure and right true cord (B: blue arrow). Following laser excision of the vocal cord lesions, subglottic extension (C: blue arrow) was visible, indicating an advanced staged tumour.

Discussion
Laryngeal cancer is the second most common head and neck cancer in Malaysia, more commonly seen in patients of advanced age, with a mean of 59 years. Principally laryngeal cancer is a disease of men, and is highly associated with smoking and alcohol consumption. In Malaysia, the majority of laryngeal cancer patients are Chinese, who account for 54% of cases, followed by Indians (23%) and Malays (19%). The reported gender distribution is 7.6:1 male to female, with an obvious predilection to the male gender. Population-based studies of laryngeal cancer in other parts of the world have reported similar predilections to men, with male to
female ratios between 8.4:1.6 and 30:1. The higher risk of developing laryngeal cancer is directly related to the increased prevalence of unhealthy habits like tobacco smoking and alcohol consumption among males. A recent study documented an increased risk in women who were first-hand and passive smokers, considerably reducing the male to female ratio.

The main causative factors for laryngeal cancer are tobacco smoking and alcohol consumption. Various studies have shown that these factors have a synergistic effect on the development of laryngeal cancer. It is well documented that derivatives from commercially prepared tobacco act as carcinogens in the epithelium of the larynx and disrupt division and proliferation of cells, triggering carcinogenesis. Examples of these carcinogenic derivatives include polycyclic aromatic hydrocarbons, N-nitrosamines, aromatic amines, aldehydes and volatile organic hydrocarbons. Studies have shown that the tobacco-specific nitrosamine 4-(methylnitrosamino)-1-(3-pyridyl)-1-butanone upregulates oncogenic pathways linked to head and neck cancer. The past decade has seen the emergence of electronic cigarettes (e-cigarettes), which 13 – 50% of tobacco smokers have been found to also use. Although e-cigarettes are safer than tobacco products because they do not contain nitrosamines, scientific evidence regarding their carcinogenic effect is limited due to a lack of long-term data and heterogeneity in the chemical compounds found in e-cigarettes. Other risk factors for laryngeal cancer include gastroesophageal reflux disease and certain professions. Exposure to carcinogenic agents like asbestos, textile dust and strong acid mist is associated with laryngeal cancer among miners, textile workers and workers in metal industries.

Glottic cancer, which presents in its early stage with hoarseness, accounts for nearly 90% of laryngeal cancer. A study in the United States reported that 2.2% of individuals with persistent hoarseness lasting more than four weeks were found to have laryngeal cancer. Another local study reported that hoarseness was the main symptom of laryngeal cancer, followed by stridor and dysphagia. Hoarseness has a broad range of etiologies, varying from simple flu to malignancy, making the diagnosis of hoarseness challenging for a general practitioner. A history of intermittent hoarseness with a normal voice in between episodes of hoarseness, an association with upper respiratory tract infection or an exacerbation with allergy and reflux symptoms suggest benign causes of hoarseness. Conversely, persistent and progressive hoarseness is more likely to have a malignant cause. Presence of other symptoms and signs such as dysphagia, dyspnoea, aspiration, haemoptysis, otalgia, stridor, neck mass and weight loss are irrelevant, as they suggest advanced disease. Throat examination in a patient with laryngeal carcinoma is usually normal, making endoscopic visualisation of the larynx by an otolaryngologist, the only way to detect early lesions.

Two local studies conducted in Malaysia reported that a significant percentage of patients with laryngeal cancer (75%) presented in an advanced stage requiring aggressive surgical treatment with significant postoperative functional morbidities. These local scenarios raise concerns over late presenting patients with laryngeal cancer seeking medical advice. We would like to educate the public and primary health care providers regarding the importance of early detection and prompt referral to a tertiary centre for further evaluation. A patient presenting with persistent or progressive hoarseness, with risk factors such as being male and a chronic smoker or alcohol consumer, should raise suspicions of an underlying malignant process. The presence of this alarming triad warrants prompt and careful evaluation by a trained otolaryngologist. Early referral increases the likelihood of conservative treatment protocols with superior functional and oncologic outcomes.
How does this paper make a difference to general practice?

- Red flag triad in a patient presenting with hoarseness includes:
  - Persistent or progressive hoarseness lasting more than two weeks
  - Male gender
  - Presence of a risk factor such as tobacco or alcohol consumption
- Presence of these red flags mandates referral to an otolaryngologist for prompt endoscopic examination (Figure 3).

- In laryngeal cancer, early referral to an otolaryngologist increases the likelihood of conservative treatment protocols with superior functional and oncologic outcomes.

References

CASE REPORT

Tubotympanic cholesteatoma

Darshini Nagarajah, Mohd Khairi Md Daud, Nur Syazwani Salehuddin, Nik Adilah Nik Othman


Abstract

Cholesteatoma always occur in the atticoantral type and in marginal perforation. We report a case of cholesteatoma that occurred as a tubotympanic type of perforation.

Introduction

Chronic suppurative otitis media (CSOM) is a longstanding chronic inflammation of the mucoperiosteal lining of the middle ear cleft that involves unrelied hearing loss and the constant threat of microbial invasion of the middle ear, especially in the poor socioeconomic group. Prevalence surveys revealed that the global burden of illness from CSOM involves 65–330 million individuals with draining ears, of which 60% suffer from significant hearing loss.1 It is the third most common cause of hearing loss in children after impacted wax and otitis media with effusion.2 Those who do not receive treatment for this condition may end up with profound hearing loss.3 A chronic discharging ear should alert primary care health professionals to investigate further and refer to an otorhinolaryngology (ORL) surgeon for a second opinion. We report a patient who presented with perforation at the pars tensa and was complicated by cholesteatoma formation.

Case Presentation

We report on a 59-year-old patient who was an active smoker with an unknown medical illness and presented with recurrent left ear discharge associated with reduced hearing and tinnitus since young adulthood. He did not have any active symptoms in the right ear. Regarding the ear discharge, he described it as painless with a copious amount of yellowish, non-foul-smelling discharge that occurs throughout the day. He had experienced reduced hearing in his left ear for 5 years, which worsened during active persistent otorrhea. However, he sought treatment at a private specialist centre when he noticed that the left ear discharge persisted for nearly 1 month. The discharge was not associated with upper respiratory tract infection or allergies. He kept his ears dry and denied using a cotton bud to clean his ears. He further explained that he also had tinnitus that was buzzing in nature with an intermittent high-pitched sound that was non-pulsatile. He was able to sleep at night and there was no noticeable disturbance to his daily activities. He was comfortable using the right ear for his phone conversations. He denied any vertigo, facial weakness, headache and nasal or throat symptoms. On examination, he was alert and conscious with no facial weakness or pain. An anterior rhinoscopy and throat examination revealed normal findings. Otoscopic examination showed a left central perforation with keratin and mucopus with intact pars flaccida (Figure 1). There was a healed perforation on the right tympanic membrane. Pure tone audiometry showed severe conductive hearing loss in the left ear.

Figure 1. Otoendoscopy of the left ear showed central perforation with keratin debris within the middle ear cavity.
(HRCT) of the temporal bone revealed soft tissue lesions occupying the entire middle ear, aditus antrum and mastoid antrum (Figure 2). There was a remnant of the incus but the remaining ossicles were not visualised.

The patient underwent left modified radical mastoidectomy and tympanoplasty type 3 for eradication of the disease. The ear was noted to be dry and the mastoid bowl was well epithelised at 1 year post-surgery.

**Discussion**

Cholesteatoma is a well-demarcated non-neoplastic lesion producing keratin squamous epithelium in the fibrous tissue matrix with a bony erosion property. It can be further categorised into congenital and acquired. The acquired variety is further subclassified into primary and secondary.4

The most common sites of cholesteatoma origin are at the posterior epitympanum, posterior mesotympanum and anterior epitympanum. Secondary cholesteatoma is most commonly observed in attic or marginal perforations. Cholesteatoma occurrence in CSOM with central perforation is very rare and only a few cases have been reported.

Graham et al. first described tympanic membrane cholesteatoma (TMC) in 1984. They noted four cases of TMC with central perforation lined by the undersurface of the tympanic membrane desquamating the epithelial debris into a promontory.5 Yamatodani et al. studied 17 cases of secondary acquired cholesteatoma.6 They concluded that it is a rare disease that is more prevalent in women than in men and often treated surgically at a relatively advanced age. They also concluded that secondary acquired cholesteatoma is prone to result in poor hearing improvement. In this study, the improvement of postoperative hearing favoured the younger age group.

Furthermore, Bluestone and Klein found that out of 1024 cholesteatoma patients, 6% had central perforation.7 Additionally, Rout et al. described a 3.4% prevalence of cholesteatoma in the case of CSOM with central perforation in their study. This study also revealed a keratinising squamous epithelium on the tympanic side of the tympanic membrane or in the tympanic cavity, which was occasionally found during surgery. This finding was observed in 28 out of 2948 patients with central perforation and no co-existing pathology suggesting cholesteatoma.8 Barath et al. noted that patients with middle ear cholesteatoma presented with a chronic discharging ear in 33–67% of cases, with hearing loss in 60–80%, facial nerve palsy in 20–64% and vertigo in 30–60%.9

HRCT temporal has been the ideal imaging for diagnosing cholesteatoma due to its excellent spatial resolution and high sensitivity in both the free middle ear and mastoid regions. Typical findings of cholesteatoma have been reported as sharply marginated expansile soft tissue lesions, retraction of the tympanic membrane, scutum blunting and the erosion of the ossicles and tegmen tympani.9 CT findings of dehiscent lateral semicircular canal support the diagnosis of labyrinthine fistula with a prevalence of 5–10% and associations with episodic vertigo, tinnitus and hearing loss.9

CSOM is traditionally classified as either atticoantral (unsafe) or tubotympanic (safe). Notably, cholesteatoma is associated with the former type. Since cholesteatoma has recently been discovered to also occur in the pars tensa (albeit rarely), many otologists have described CSOM as a squamous (cholesteatoma) or mucosal disease. The European Academy of Otolaryngology and Neurotology and the Japanese Otolological Society have jointly classified cholesteatoma as pars flaccida, pars tensa or a combination of both.10

**Conclusion**

This case study suggests that no perforation is safe in CSOM, including central perforation. Thus, a chronic discharging ear even with tubotympanic perforation should be carefully examined to exclude the possibility of cholesteatoma.
References


TEST YOUR KNOWLEDGE

A diabetic lady with difficulty in breathing
Seng Wee Cheo, Khai Lip Ng, Qin Jian Low

Keywords:
Tuberculosis, air crescent sign, dyspnea

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Introduction
Dyspnoea is a common respiratory symptom that clinicians encounter in daily clinical practice. It is defined as a subjective experience of breathing discomfort that consists of qualitatively distinct sensations that vary in intensity.\(^1\) The various causes of dyspnoea can be broadly divided into cardiogenic causes, respiratory causes, neuromuscular causes and others.\(^2\) In approaching a patient who complains of dyspnoea, we must systematically evaluate him/her to obtain a definitive diagnosis. Investigations that can be performed include arterial blood gas analysis, electrocardiography, echocardiography and chest radiograph. Here, we illustrate a patient who complained of breathing difficulty.

Case Presentation
A 46-year-old Filipino woman with non-insulin-dependent diabetes mellitus and previous pulmonary tuberculosis (4 years ago prior) presented to a local health clinic with chronic productive cough with greenish sputum and fever (3 months in duration) associated with loss of appetite and weight loss. She denied shortness of breath or haemoptysis. On examination, there was bronchial breathing in the left upper lobe. Other systemic examinations were unremarkable. Her sputum was positive for acid-fast bacilli and she was started on antituberculous therapy.

Two months later, she presented to the clinic with worsening dyspnoea and fever (1 week in duration). She denied haemoptysis. On examination, she was alert and mildly tachypneic. Her respiratory examinations showed bronchial breathing in the left upper zone and dullness on percussion. Other systemic examinations were unremarkable. Her full blood count showed a haemoglobin of 11.9 g/dl, total white blood cell count of 16.2x10^9/L and platelet count of 210x10^9/L. Her renal profile and liver function test were normal. Arterial blood gas showed no evidence of respiratory failure. A chest radiograph was also performed (Figure 1).

Questions and Answers:
1. Describe the chest radiograph.

Figure 1 presents the PA erect view chest radiograph of the patient, which shows a radiopaque cavitary lesion at the left upper lobe surrounded by a crescent-shaped radiolucency typical of an air crescent sign. The right lung field, ribs and heart appear normal.

2. What is the most likely diagnosis and differential diagnosis?

The most likely diagnosis is pulmonary aspergilloma. The fundamental diagnosis is based on the history of previous tuberculosis and the current chest radiograph showing an air crescent sign. The diagnosis is confirmed by Monod’s sign (see below). Differential diagnoses to consider include pulmonary tuberculosis, Rasmussen aneurysm, lung abscess, hydatid cyst and cavitory lung cancer.\(^3\)

3. What other investigations can be performed?

a) Sputum acid-fast bacilli – To check for active pulmonary tuberculosis.
b) Sputum for culture and sensitivity – To culture for bacterial, mycobacterial and fungal organisms.
c) Serum Aspergillus IgG – To confirm the diagnosis of aspergillosis.\(^4\)
d) Bronchoscopy – In patients with a negative fungal culture, bronchoscopy should be performed to collect a bronchial washing sample and exclude malignancy.5

e) Computed tomography of the thorax – To further characterise the air crescent sign and differentiate between the differential diagnoses. Contrast-enhanced CT of the thorax may help to identify Rasmussen aneurysm and may also help in identifying cavitary lung cancer.6

4. Outline the management plan
Most aspergillomas are asymptomatic and their cavity is often isolated. Thus, there is a limited role for systemic antifungals. Patients should be followed up and monitored for disease complications (e.g., infections and haemoptysis). A single symptomatic lesion is best treated with surgical resection.4 Patients who develop massive haemoptysis may require embolisation or surgery.

Case Progress
Returning to our case, the patient’s chest radiograph showed a radiopaque cavitary lesion at the left upper lobe, which was surrounded by a crescent-shaped radiolucency suggestive of an air crescent sign. The patient subsequently had a chest radiograph performed in the decubitus position, in which the cavitary lesion showed a change in position. This is typical of Monod’s sign, thus confirming the diagnosis of aspergilloma (Figure 2). Her sputum cultures were negative for bacterial, mycobacterial and fungal organisms.

She was then counselled for serum Aspergillus IgG, bronchoscopy and computed tomography of the thorax. She refused further investigation due to financial reasons. She was treated with a course of antibiotics for superimposed bacterial infection and then improved. On follow-up after completion of anti-tuberculous therapy, her chest radiograph remained the same and she did not have any haemoptysis.

Discussion
An air crescent sign is a radiological sign involving a crescent-shaped radiolucency surrounding a parenchymal consolidation or nodular opacity.7 Monod’s sign describes the mass or consolidation move to the dependent area.8 An air crescent sign can be seen in the radiograph or computed tomography. By far, the most common cause of an air crescent sign is aspergilloma. Differential diagnoses could include pulmonary tuberculosis, pulmonary hydatid cyst, Rasmussen aneurysm and lung carcinoma.9

In light of previous tuberculosis and the presence of an air crescent sign, we believe that our patient most likely had aspergilloma. Moreover, the air crescent sign persisted before and after treatment with antibiotics and anti-tuberculous therapy. On the other hand, Aspergillus fumigatus is the most common Aspergillus species that causes disease in humans. Pulmonary aspergillosis usually occurs in patients with underlying lung disease (e.g., sarcoidosis, cystic fibrosis and old tuberculosis). In old tuberculosis, there are residual cavities from a previous infection that aspergillomas tend to form within.10 In a British study, it was estimated that chronic pulmonary aspergillosis complicates 4.9–6.3% of all previously treated tuberculosis. Notably, it is more common in patients with cavitary lung lesions.11

Aspergilloma usually occurs in immunocompetent patients, with most aspergilloma being asymptomatic. Symptoms are non-specific, with some patients presenting...
How does this paper make a difference to general practice?

The chest radiograph is widely used in clinical practice. As medical practitioners, we must be able to recognize important radiological signs and correlate them with the clinical presentation of patients. Through this case, we aim to illustrate the importance of the air crescent sign.

In conclusion, although an air crescent sign is an important clinical sign, it is not pathognomonic for aspergilloma. Thus, we must always interpret this radiological sign according to the clinical presentation of patients.

Conflicts of Interest

The author declared that they have no conflicts of interest.

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References


with cough, fever, chest pain and hemoptysis. Aspergilloma can typically be managed with expectant management. However, one must remember that massive haemoptysis is a potentially life-threatening complication and the necessary steps must be taken to treat it. Systemic anti-fungals have a limited role since the cavity is often isolated.

In conclusion, although an air crescent sign is an important clinical sign, it is not pathognomonic for aspergilloma. Thus, we must always interpret this radiological sign according to the clinical presentation of patients.
TEST YOUR KNOWLEDGE

Hoarseness in an older adult: Ortner syndrome

Wei Ji Koh, Mawaddah Azman


**Keywords:**
Voice disorders, dysphonia, recurrent laryngeal nerve injuries.

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**Case summary**

A 71-year-old man who was a chronic smoker with a background history of essential hypertension presented with hoarseness for 5 months. The symptom was sudden in onset and associated with vocal fatigue. The symptom was not worsening, and no aspiration symptoms were noted. There was no noisy breathing, dyspnoea, dysphagia or neck swelling. Laryngoscopic examination showed left vocal fold paralysis with phonation gap. No growth was seen at all laryngeal and hypopharyngeal subsites. The rest of the head and neck, chest, upper limbs and neurovascular examination were unremarkable. Baseline blood investigations, including a full blood count and a renal profile, were within the normal ranges. A plain chest radiograph was taken as part of the radiological investigation (*Figure 1*).

**Questions**

1) What abnormality is seen in the radiograph?
2) What differential diagnoses arise from an older adult presenting with chronic hoarseness?
3) What complication can potentially arise from the left vocal fold paralysis?
4) List the management for the above condition.

**Answers**

1) Description of the chest radiograph:
   a. There is enlargement of the aortic knob and widening of the superior mediastinal silhouette. The heart and lungs otherwise appear normal.
2) Differential diagnoses for an older adult presenting with chronic hoarseness
   a. Inflammation: chronic laryngitis, tuberculosis, syphilis
   b. Tumours
      i. Malignant: glottic carcinoma
      ii. Benign: vocal nodule, vocal polyp, vocal cyst
   c. Paralysis: unilateral recurrent laryngeal nerve paralysis secondary to iatrogenic cause (40%), for example, thyroidectomy, neck surgery, thoracic surgery and spine surgery; idiopathic cause (25%); malignant cause (25%), for example, lung carcinoma, oesophageal carcinoma, metastatic lymphadenopathy; and other rare causes like Ortner syndrome (less than 5%)1

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*Figure 1*. Plain chest radiograph
3) Complication
   a. Aspiration pneumonitis secondary to non-compensated recurrent laryngeal nerve palsy

4) Management
   a. Medical management of thoracic aortic aneurysm
      i. Smoking cessation.
      ii. Good control of hypertension to aim for blood pressure of ≤120/80mmHg.
      iii. Beta-blockers like propranolol and metoprolol have been shown to slow the rate of growth by reducing the stress to the aortic wall. Losartan, an angiotensin-receptor blocker, interferes with the signalling of the TGF-beta protein and slows the growth of aortic aneurysms in Marfan syndrome.
      iv. Serial follow-up CT angiogram to assess the progression and size of the aneurysm in patients managed conservatively.
   b. Surgical management of thoracic aortic aneurysm
      i. Open repair of aneurysm is considered in symptomatic patients or aneurysm size of 5cm or more in asymptomatic patients.
      ii. Thoracic endovascular aortic repair (TEVAR) is less invasive, less expensive and carries a lower operative risk compared to standard open repair of aneurysm, especially if the patient is at high risk for open intervention.
   c. Management of recurrent laryngeal nerve palsy
      i. Voice improvement is expected within weeks or months following successful surgical intervention for the thoracic aneurysm. Hence, office injection laryngoplasty with hyaluronic acid can be performed by the laryngologist to alleviate hoarseness while waiting for definitive surgical intervention.
      ii. Permanent medialisation thyroplasty under local anaesthesia if surgical intervention is not considered or poor anaesthesia candidate.

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Conflicts of interest
All authors declare no conflicting interests.

How does this paper make a difference to general practice?
- Hoarseness in a patient is encountered regularly in daily general practice, and its subsequent management can often be elusive.
- This paper highlights the importance of considering unilateral vocal fold paralysis in an older adult who was otherwise asymptomatic of an aortic aneurysm, despite having the risk factor of essential hypertension.
- A detailed and early ear, nose and throat examination in an older adult with risk factors presenting with hoarseness is mandatory to exclude an upper aerodigestive tract malignancy.
- A simple chest radiograph is useful in further management of such patients to confirm the diagnosis of Ortner syndrome or exclude aspiration pneumonitis and lung cancer.
- In addition to avoiding unnecessary invasive diagnostic procedures, a prompt diagnosis provides patients with reassurance and prevents unnecessary anxiety over the possibility of malignancy.
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A journey of a thousand miles begins with a single step: Applying evidence-based medicine to answer clinical questions

Peter Seah Keng Tok


Dear Editor-in-Chief,

I read the editorial ‘We need a research plan’ with great interest. The author highlighted the importance of going beyond exploratory studies and outlined the subsequent stages of health intervention development, evaluation and implementation. Going through the full cycle of the ‘research journey’ is indeed rewarding (for both patients and researchers alike), and I wish to thank the author for his pearls of wisdom.

Taking a leaf out of the research framework proposed in the editorial piece, perhaps it might also be useful to explore (exploratory) why most research articles are exploratory in nature. In this regard, a cross-sectional study of specialists in Malaysian government hospitals that explores their attitudes towards, barriers to and facilitators for conducting research may offer some insights. Frequently mentioned barriers that may be relevant include lack of funds, red tape in obtaining approvals, and the inadequacy of research skills, training opportunities and guidance from mentors. More often than not, studies that are beyond exploratory involve interventional research that may be resource-intensive, subject to higher scrutiny by ethical review boards (aptyly so) and require a certain level of expertise or technical know-how.

While stakeholders do their part in the planning and implementation of strategies to break these barriers, we should continue to remain inquisitive and take a step further whenever possible. For example, when we face clinical conundrums in the provision of patient care, the systematic approach to the acquisition, appraisal and application of existing research evidence should always be practised to guide healthcare decisions. Indeed, that is one of the popular definitions of evidence-based medicine (EBM). Evidence-based case reports also illustrate the process of how evidence can be applied at all stages of patient care. Additionally, when we apply EBM in our daily practice, we are essentially exploring and reviewing (exploratory) existing evidence pertaining to the clinical questions we have in mind, which will ultimately lead us to identify crucial gaps that may necessitate further investigation or intervention. Thereafter, we can meaningfully proceed to the next stages of developing and evaluating health interventions.

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