**Title:** Patterns of prescribing in the management of gastro-oesophageal reflux in infants aged 0 to 1 year in Scotland.

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Abstract:

Title: Patterns of prescribing in the management of gastro-oesophageal reflux in infants aged 0 to 1 year in Scotland.

Objective: To determine trends over time and geographical differences in prescribing for gastro-oesophageal reflux (GOR) and gastro-oesophageal reflux disease (GORD) in infants aged 0 to 1 year in Scotland.

Methods: National prescribing data obtained from the Information Services Division of NHS Scotland (ISD Scotland) was quantitatively analysed using the software tool Minitab16

Results: Prescribing of the three key medicines, alginate, omeprazole and ranitidine, used in the management of GOR and GORD in infants aged 0 to 1 year increased in Scotland over the 7 years between 2010 and 2016. Although the prescribing for alginate showed the greatest absolute increase rising from 15.7% in 2010 to 24.7% in 2016, the prescribing rate for ranitidine increased four-fold and for omeprazole three-fold. The data also showed much variation in the patterns of prescribing across NHS Boards.

Conclusions: The rise in the prescribing rates of alginate, omeprazole and ranitidine is a cause for concern given the uncertainty regarding the efficacy of these medicines in this age group and that omeprazole and ranitidine are not licensed for use in infants under one year of age in the UK. While the data suggest that the prescribing rate of alginate may have stabilised, the increasing trends for omeprazole and ranitidine show no sign of abating and this may have financial implications for the NHS as well as potential ethical and health implications for young infants.

Keywords: Regurgitation; Gaviscon, Ranitidine, Omeprazole

What is already known?
- The use of pharmaceutical products to manage GOR has increased in some countries
- Evidence supporting the use of medicines in the management of GOR are equivocal
- Ranitidine and omeprazole are not yet licensed for use in infants under 1 year old age.

What this study adds?
- There is an increasing use of alginate (Gaviscon), ranitidine (H2RA) and omeprazole (PPI) in the management of symptoms of GOR/ GORD in Scotland.
- There is regional variation in the use of these medicines to management symptoms of GOR
- Practitioners may not follow the stepped care approach advocated by NICE (2015)
**Introduction**

Anecdotal evidence from discussions with health visitors suggests an increase in the diagnosis and prescribing for gastro-oesophageal reflux (GOR) in Scotland. Furthermore, evidence suggests that the use of pharmaceutical products to manage symptoms of GOR in infants is increasing internationally (Barron et al, 2007, Khoshoo et al, 2007, Rimmer and Hiscock, 2013; De Bruyne et al, 2014) and is not just a Scottish issue. A large retrospective observational study (Barron et al, 2007) undertaken in the United States found the use of proton pump inhibitors (PPI) increased four-fold between 2000 and 2003. In Belgium a retrospective observational study (De Bruyne et al, 2014) found a seven-fold increase in prescribing of all anti-reflux medicines between 1997 and 2009, but the increase was most significant in the prescribing of H2 receptor antagonists (H2RA) and PPIs. Interestingly an Australian study (Rimmer and Hiscock, 2013) that focused on crying infants suggests that in Australia some paediatricians are misdiagnosing the problem of crying in infants, resulting in GOR and gastro-oesophageal reflux disease (GORD) being over-diagnosed and leading to inappropriate prescribing of PPIs. A more recent cross-sectional survey (Kirby et al, 2016) however, explored the attitudes and practices of 400 general practitioners in Australia and found a high percentage (87%) of general practitioners in the study prescribed H2RAs and PPIs to infants with symptoms of GOR. This study, therefore, sought to examine current data held by the Information Services Division of NHS Scotland (ISD Scotland) in order to assess the validity of this anecdotal evidence and to determine overall trends and regional differences in prescribing for GOR in infants in Scotland. The Information Services Division of NHS Scotland (ISD Scotland) is part of National Services Scotland (NSS) and provides the national statistical data that informs decision making and planning in the National Health Service (NHS) in Scotland (ISD Scotland, 2010).

**Methods**

Prescribing data for the key medicines used to manage GOR and GORD in the 0 to 1-year age group for the whole of Scotland, and across all 14 NHS Boards, for the seven-year period from 2010 and 2016 (inclusive) were obtained from ISD Scotland to identify patterns of prescribing. Data prior to 2010 were not available due to different methods of recording data. For the purposes of this study, the age range of infants prescribed medicine was restricted to 0 to 1 year because ISD Scotland record prescribing rates in whole year age groups. More detailed data regarding the age in months of infants was not available. The data gathered include the number of items dispensed and paid for, the patient count, and the prescribing rate for the key medicines used to manage GOR and GORD in Scotland and the UK: Gaviscon (Alginate), ranitidine (H2RA), omeprazole (PPI).
Data Analysis
Secondary analysis of the data was then undertaken to explore the objectives of this study. The software tool, Minitab 16, was used to manage and analyse the data obtained concerning the 14 NHS Boards in Scotland. In addition to graphical comparisons, confidence intervals were constructed to provide an indication of the precision of the rates and linear regression analysis was used to assess apparent trends. The population sizes for Scotland and the NHS boards for the study period were reviewed and it was noted that the population sizes in Orkney, Shetland and the Western Isles are relatively low. Hence, relatively wide confidence intervals are computed for these boards which reflect the lower precision associated with their rates. In a few particular instances where the number of prescriptions was very low (<10), confidence intervals would be considered invalid and, thus, were not constructed. However, these instances do not feature amongst the particular results highlighted in this paper.

Results
The data reveal that across the whole of Scotland, the prescribing rate for all three medicines increased during the seven years between 2010 and 2016. Evidently, the prescribing rate for alginate was persistently much higher than for the other pharmaceutical products used in the management of GOR and GORD in infants (Table 1).

The higher rate in alginate prescribing is not unexpected as it reflects NICE (2015) guidance that recommends a two-week trial of alginate therapy in breastfed babies. It is also in line with the stepped-care approach applied to formula fed babies that have shown no improvement following the introduction of a thickened formula.

Although the prescribing rate for alginate shows the greatest absolute increase, from 15.7% in 2010 to 24.7% in 2016, the prescribing rate for ranitidine increased over four-fold from 2.3% in 2010 to 9.7% in 2016, and for omeprazole it increased over three-fold from 0.9% in 2010 to 3.2% in 2016. It is also interesting to note that whilst the prescribing rates for both omeprazole and ranitidine have risen steadily, the prescribing rate for alginate began to level out from 2014. Confidence intervals for the ‘true’ prescribing of alginate, omeprazole and ranitidine are also presented in Table 1. The intervals are typically narrow and confirm that perceived differences over time cannot be attributed to random fluctuation.
**Table 1:** Prescribing rate and 95% Confidence Intervals for Scotland 2010 – 2016.

<table>
<thead>
<tr>
<th>Year</th>
<th>Alginate</th>
<th>Omeprazole</th>
<th>Ranitidine</th>
</tr>
</thead>
<tbody>
<tr>
<td>2010</td>
<td>15.75% (15.43 - 16.07)</td>
<td>0.89% (0.81 - 0.96)</td>
<td>2.33% (2.21 - 2.45)</td>
</tr>
<tr>
<td>2011</td>
<td>18.20% (17.85 - 18.54)</td>
<td>1.19% (1.11 - 1.28)</td>
<td>3.02% (2.88 - 3.16)</td>
</tr>
<tr>
<td>2012</td>
<td>19.67% (19.31 - 20.02)</td>
<td>1.40% (1.30 - 1.49)</td>
<td>3.6% (3.51 - 3.82)</td>
</tr>
<tr>
<td>2013</td>
<td>21.97% (21.59 - 22.35)</td>
<td>1.85% (1.74 - 1.96)</td>
<td>4.97% (4.78 - 5.15)</td>
</tr>
<tr>
<td>2014</td>
<td>24.28% (23.87 - 24.68)</td>
<td>2.49% (2.36 - 2.62)</td>
<td>6.83% (6.61 - 7.04)</td>
</tr>
<tr>
<td>2015</td>
<td>24.80% (24.39 - 25.20)</td>
<td>2.86% (2.72 - 3.00)</td>
<td>8.17% (7.94 - 8.41)</td>
</tr>
<tr>
<td>2016</td>
<td>24.72% (24.31 - 25.13)</td>
<td>3.26% (3.11 - 3.41)</td>
<td>9.66% (9.40 - 9.92)</td>
</tr>
</tbody>
</table>

The data were further analysed to examine the prescribing pattern for the three drugs in each of the 14 NHS Boards in Scotland. The prescribing rates for omeprazole and ranitidine in each NHS Board from 2010 and 2016 are illustrated in Figures 1, and 3. The prescribing rates of these medicines were ranked and the top three ranking NHS Boards for all three medicines between 2010 - 2016 are presented in Table 2.

There is clear variation in the pattern of prescribing for each drug, across the NHS Boards with different boards featuring amongst the top ranks for each drug. For alginate, Lanarkshire features in the top three ranks in all but one of seven years and is ranked highest in 2016. While the prescribing rates of alginate appear to have stabilized at other high-prescribing boards, the Lanarkshire rate has continued to increase approximately linearly and over the full study period from 19.08% to 32.48%. Forth Valley features in the top three ranks for each year apart from 2016; in fact, the rate dropped in each of the last two study years. At Greater Glasgow and Clyde, the alginate prescribing rate increased sharply from 17.05% in 2010 to 30.11% in 2015, and despite a reduction to 27.78% in 2016 still held second top ranking. Grampian was initially the highest prescriber of alginate but does not appear in the top 3 ranks after 2013. The increase at Grampian from 2010 to 2016 of 3.86% is relatively low.

Lothian, Dumfries and Galloway, Fife and Lanarkshire were found to have the highest prescribing rates for omeprazole. The prescribing rate for omeprazole showed an increasing trend in each of these boards over the study period with Lothian top-ranked in each of the
seven years, rising from 1.76% to 5.65%. In Dumfries and Galloway, the prescribing rate for omeprazole rose sharply in 2016 to 5.4%, almost level with Lothian.

With regard to ranitidine, over the full study period Grampian clearly had the highest prescribing rate, rising linearly from 4.87% to 14.35%. Forth Valley and Shetland also feature consistently near the top of the Ranitidine rankings. (Whilst the individual confidence intervals for Shetland are relatively wide due to relatively small population numbers, the cumulative evidence over the study period is substantial).

It is also interesting that, in contrast to having one of the highest prescribing rates for omeprazole, Dumfries and Galloway has the second lowest prescribing rate in the mainland boards for ranitidine. Conversely, Grampian has the highest prescribing rate for ranitidine but the second lowest mainland board prescribing rate for omeprazole. Compared to most of the other Boards, Ayr and Arran had low prescribing rates for all three drugs over the study period although these still showed underlying increasing trends.

Figure 1: Prescribing rate of omeprazole by NHS Board
Figure 2: Prescribing rate of ranitidine by NHS Board
Table 2. Ranking of the NHS Boards with the highest prescribing rates for alginate, omeprazole and ranitidine (2010 – 2016)

<table>
<thead>
<tr>
<th></th>
<th>Alginate</th>
<th>Omeprazole</th>
<th>Ranitidine</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rank 1</td>
<td>Rank 1 (Highest)</td>
<td>Rank 2</td>
<td>Rank 3</td>
</tr>
<tr>
<td>2010 Rate</td>
<td>Grampian</td>
<td>Lanarkshire</td>
<td>Forth Valley</td>
</tr>
<tr>
<td>(per 100)</td>
<td>20.16 (19.17 - 21.14)</td>
<td>19.08 (18.14 - 20.02)</td>
<td>17.62 (16.34 - 18.91)</td>
</tr>
<tr>
<td>(Lower</td>
<td>Lanarkshire</td>
<td>Lanarkshire</td>
<td>Lanarkshire</td>
</tr>
<tr>
<td>Upper CI</td>
<td>22.53 (21.51 - 23.54)</td>
<td>21.40 (20.40 - 22.39)</td>
<td>19.87 (18.54 - 21.20)</td>
</tr>
<tr>
<td>2011 Rate</td>
<td>Forth Valley</td>
<td>Forth Valley</td>
<td>Lanarkshire</td>
</tr>
<tr>
<td>(per 100)</td>
<td>24.31 (22.83 - 25.80)</td>
<td>23.58 (22.55 - 24.61)</td>
<td>23.35 (22.33 - 24.38)</td>
</tr>
<tr>
<td>(Lower</td>
<td>Lanarkshire</td>
<td>Lanarkshire</td>
<td>Lanarkshire</td>
</tr>
<tr>
<td>Upper CI</td>
<td>25.69 (24.20 - 27.17)</td>
<td>25.18 (24.44 - 25.93)</td>
<td>24.67 (23.61 - 25.73)</td>
</tr>
<tr>
<td>2012 Rate</td>
<td>Gt Glasgow &amp; Clyde</td>
<td>Grampian</td>
<td>Lanarkshire</td>
</tr>
<tr>
<td>(per 100)</td>
<td>27.60 (26.38 - 28.37)</td>
<td>25.18 (24.44 - 25.93)</td>
<td>25.95 (24.93 - 26.97)</td>
</tr>
<tr>
<td>(Lower</td>
<td>Forth Valley</td>
<td>Gt Glasgow &amp; Clyde</td>
<td>Lanarkshire</td>
</tr>
<tr>
<td>Upper CI</td>
<td>25.72 (25.72 - 28.86)</td>
<td>25.18 (24.44 - 25.93)</td>
<td>25.95 (24.93 - 26.97)</td>
</tr>
<tr>
<td>2013 Rate</td>
<td>Gt Glasgow &amp; Clyde</td>
<td>Lanarkshire</td>
<td>Lanarkshire</td>
</tr>
<tr>
<td>(per 100)</td>
<td>30.11 (29.31 - 30.91)</td>
<td>29.96 (28.88 - 31.04)</td>
<td>25.07 (23.53 - 26.62)</td>
</tr>
<tr>
<td>(Lower</td>
<td>Lanarkshire</td>
<td>Lanarkshire</td>
<td>Lanarkshire</td>
</tr>
<tr>
<td>Upper CI</td>
<td>32.48 (31.40 - 33.57)</td>
<td>29.96 (28.88 - 31.04)</td>
<td>25.07 (23.53 - 26.62)</td>
</tr>
<tr>
<td>2014 Rate</td>
<td>Lanarkshire</td>
<td>Lanarkshire</td>
<td>Lanarkshire</td>
</tr>
<tr>
<td>(per 100)</td>
<td>27.78 (26.99 - 28.56)</td>
<td>27.78 (26.99 - 28.56)</td>
<td>25.07 (23.53 - 26.62)</td>
</tr>
<tr>
<td>(Lower</td>
<td>Lanarkshire</td>
<td>Lanarkshire</td>
<td>Lanarkshire</td>
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**Discussion**

The results show an estimated annual increase in rate of 1.60 percentage points per year in the use of alginate, 1.27 in the use of ranitidine, and 0.41 in the use of omeprazole in infants aged 0-1 year in Scotland over the seven years from 2010 to 2016. This outcome mirrors the findings of previous studies undertaken in United States (between 1999 and 2004 in respect
of PPI use) and Belgium (between 1997 and 2009 concerning acid suppressant medication) that reported an increase in the use of PPIs and H2RAs in infants aged 0 to 1 year (Barron et al, 2007; De Bruyne et al, 2014). This study, however, has also highlighted significant regional variation in the pattern of prescribing of alginate, omeprazole and ranitidine in Scotland. The reason for the regional variation is unclear but may be linked with the alignment of NHS Boards to major paediatric centres, such as Glasgow, Edinburgh, and Aberdeen and their associated protocols and prescribing preferences, or to local guidelines and recommended practices in each NHS Board area. Other possible reasons for the variation in prescribing rates may relate to regional differences in affluence or deprivation, or the accessibility of health services, however further research is needed to provide more definitive answers. Given the current deficit in the number of health visitors and general practitioners working in Scotland (Scottish Government, 2014, ISD Scotland, 2016) the variation in prescribing rates may also be associated with staffing levels in NHS Boards and the availability of these health professionals, particularly health visitors, to provide adequate support with the recommended conservative management of symptoms of GOR to concerned and anxious parents.

A key factor may relate to the subjective nature of diagnosis and the lack of robust criteria to distinguish between a diagnosis of GOR and GORD (NICE, 2015). NICE (2015) defines GORD as symptoms of GOR that are severe enough to merit medical treatment, however the notion of ‘severe enough’ is subjective and open to interpretation with no clear delineation between GOR and GORD. Furthermore, infants cannot describe or communicate the extent of the discomfort of the symptoms of GOR, therefore the severity of the regurgitation and discomfort will be conveyed by the parents who, caring for the child, and being concerned about the impact on the baby’s health and wellbeing may perceive the regurgitation and possetting to be ‘severe enough’ to merit medical treatment (Orenstein, 2010).

Whilst the lack of clarity regarding diagnosis may have led to the over-diagnosis or misdiagnosis of GOR and GORD, it could also be argued that in recent years, diagnosis has improved resulting in more cases of GOR and GORD now being identified. This may be an explanation for the rise in prescribing of alginate, omeprazole and ranitidine in infants. Alternatively, it has been questioned whether the identified symptoms of GOR can actually be attributed to GOR and not another cause (NICE, 2015). For example, symptoms of cows milk protein allergy and lactulose intolerance are akin to that of GOR and GORD, further adding to the complexity of forming a diagnosis (Onyeador, Paul, and Sandhu, 2014; NICE, 2015, BNF For Children, 2016). However, whilst evidence suggests that 2% to 6% of children suffer from cows milk protein allergy, which, like GOR, is most prevalent in children aged 0 to 1 year, evidence regarding lactulose intolerance in young infants is lacking (Caffarelli et al, 2010; NICE, 2011).

Nevertheless, GOR is a normal physiological event affecting over 40% of infants (Vandenplas et al, 2009; Tighe et al, 2014; NICE, 2015). Therefore, the increase in the prescribing rate of omeprazole or ranitidine coupled with the evidence of poor efficacy of
these medicines suggests that some infants are treated for symptoms of GOR/GORD when their symptoms are benign. This is a concern, particularly as these drugs are not yet licensed for use in infants under 1 year old and adverse effects associated with the use of some H2RA and PPI in older children have been reported (Kierkus et al, 2014; Gieruszcak-Bialek, 2015).

The interpretation, diagnosis and treatment of normal physiological conditions as medical problems requiring treatment raises questions about the medicalisation of GOR. Reflecting on the sociology of diagnosis, Jutel (2011) highlights the prerequisites for a condition to become recognised as a disease are that it is undesirable and visible. This may be the case with GOR in infants as regurgitation, possetting, crying and unsettledness are not only visible but may be perceived by parents and practitioners as unpleasant, undesirable and disagreeable. Arguably this could be a possible explanation for the potential differential diagnosis and increasing use of medicines in the management of symptoms of GOR.

Another influence may stem from the iterative relationship between medicalisation and diagnosis that is continually evolving (Jutel, 2011). The concepts of diagnosis and medicalisation are inherently linked, nevertheless they are also very different in that entwined within medicalisation is the concept of pharmaceuticalisation (Williams, Gabe, and Davis, 2008; Williams, Martin, and Gabe, 2011). In contrast to ‘medicalisation’, ‘pharmaceuticalisation’ focuses on finding potential conditions that are normal and disease free, such as baldness in men or indeed GOR, and marketing them as problems requiring pharmaceutical treatment. In the UK direct to consumer advertising by pharmaceutical companies is limited to ‘over the counter drugs’ (Medicines and Healthcare Products Regulatory Agency, 2012), however the internet is easily accessible, wide ranging and a very powerful advertising medium (Fox and Ward, 2008). Furthermore, there has been a steady increase in the use of the internet to access and acquire health related information (McMullen, 2006; Dumit, 2012). As the internet permeates people’s personal and home life it can act as a conduit for health information as well as being a powerful force influencing perceptions and changing expectations of parenthood and child care.

The data for Scotland show that from 2014 the prescribing rate for alginate started to level out, or reach a plateau, although the prescribing rates for both omeprazole and ranitidine have continued to rise steadily. As alginate for infants can be readily bought over the counter from pharmacies, it may be that more parents are buying the product themselves rather than seeking a prescription. In addition, the rising trend in the prescribing of omeprazole and ranitidine, may also reflect the stepped-care approach advocated by NICE (2015) is not being followed. An earlier European wide survey (Quitadamo et al, 2014) involving 11 countries (excluding the UK) found that the 2009 North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition and the European Society for Paediatric Gastroenterology, Hepatology, and Nutrition Guideline (NASPGHAN – ESPGHAN Guideline) was not implemented in practice and that 36% of the paediatricians surveyed prescribed PPI for infants with symptoms of GOR, and 39% of paediatricians prescribed PPI for infants with distressed behaviour and unexplained crying. Commenting on the study...
(Quitadamo et al, 2014), McCracken (2014) suggests that poor implementation of the guideline may be due to ignorance or lack of awareness of the guideline by practitioners, particularly if it was not widely published or promoted. It is possible, therefore, that some practitioners in Scotland are unaware of the existence of the NICE guideline. Alternatively, the guidelines regarding the stepped care approach may be deemed ineffective and therefore ignored (McCracken, 2014). This suggests that further research to explore the uptake and implementation of clinical guidelines by health visitors and general practitioners is needed.

Regression analysis showed a linear trend, particularly for omeprazole and ranitidine, which, if continued, suggests estimated annual increases in the prescribing of omeprazole and ranitidine. This is a concern given the uncertain efficacy of these drugs and the potential for adverse affects (Kierkus et al, 2014; Tighe et al, 2014; Gieruszczak-Bialek et al, 2015). However, also cause for concern is the cost of potentially ineffectual and unnecessary prescribing, particularly as NHS services in the UK are reported to be under enormous pressure (Lacobucci, 2017; Gullard, 2017) and in Scotland NHS Boards are reported to struggle to keep pace with increasing demand and increasing cost (Audit Scotland, 2016). Therefore, the drive for efficiency savings in health spending is paramount. Between the years ending 2013 and 2015 the cost of drugs in NHS Scotland rose by 10% (Audit Scotland, 2016). Therefore, the current evidence regarding the efficacy of these drugs suggests that this is an area where efficiency savings could be made, particularly if long term use of these drugs in the 0 to 1-year age group leads to unwarranted and adverse effects (Kirekus, et al, 2014; Gieruszczak-Bialek et al, 2015).

To our knowledge, this study is the first to describe changing patterns of practices and prescribing with regard to the management of GOR and GORD in infants aged 0 to 1 year in the UK. Previous studies have been undertaken in other countries but different health care systems do not allow for direct comparisons.

The escalation in prescribing rates of alginate, H2RA, and PPI in the 0 to 1-year age group coupled with the uncertain efficacy and lack of evidence to support the use of these drugs raises questions for clinicians and policy makers regarding practitioner prescribing behaviours, and measures to support families to implement the recommended conservative measures when caring for their child. Evidence suggests that conservative measures are sufficient in the management of symptoms of GOR in infants (Puntis, 2015, Drug and Therapeutics Bulletin, 2010; Onyeador, Paul, and Sandhu, 2010) therefore in Scotland there is clearly a role for health visitors to offer additional support to parents, giving them confidence to care for their baby and manage the symptoms of GOR conservatively. However, further research to provide evidence of the impact of the health visiting service and promotion of conservative measures in the management of GOR is needed.

While the NICE (2015) guideline advocates a stepped-care approach to the management of GOR and GORD in infants starting with conservative measures, the rise in the prescribing rates of ranitidine and omeprazole suggest that the recommendations of the
guideline are not being followed or adhered. However, as indicated (Quitadamo et al, 2014) this may be due to practitioners’ lack of knowledge of the new guidance and therefore there is a need for policy makers to raise awareness and promote the NICE (2015) guidance more widely. Alternatively, it may be that the recommendations are perceived not to work in practice suggesting further research is needed to explore the efficacy and safety of the drugs in infants.

**Strengths and Limitations**

A strength of the study is that the prescribing data obtained for secondary analysis from ISD Scotland is the most accurate, robust and reliable in Scotland (ISD Scotland, 2010). However, the study is not without limitations and weaknesses. The first limitation concerns the data for alginate or Gaviscon. This may be under-represented as some alginate preparations for young infants can be bought over the counter, hence it is possible that the use of these medicines are even higher than the ISD Scotland data would infer. A second limitation concerns the age of the infants prescribed alginate, omeprazole and ranitidine. The ISD Scotland data, do not detail whether the medicines were prescribed consistently for 12 months or whether they peaked at set ages. A further limitation concerns the reason for prescribing the medicines. Whilst alginate (Gaviscon), H2RA (ranitidine) and PPI (omeprazole) are medicines used primarily in the management of GOR and GORD, it cannot be assumed that all prescriptions were written in this regard.

**Conclusion**

Analysis of data from ISD Scotland has identified increased prescribing rates for alginate (Gaviscon), H2RA (ranitidine) and PPI (omeprazole) in the 0 to 1-year age group in Scotland, as well as significant variation in the patterns of prescribing of these drugs across NHS Boards. Given the uncertain efficacy of these drugs, especially the unlicensed drugs (ranitidine and omeprazole), this is a concern. Whilst it is acknowledged that the use of H2RA and PPI can be beneficial in acid related cases such as GORD or oesophagitis, to administer medicines unnecessarily is not only costly to the public purse but arguably unethical and not in the best interests of the child.
References

   Accessed: 16/08/2018


3. BNF For Children (2016)
   Available on-line from: https://www.medicinescomplete.com/mc/bnfc/current/

   Available on-line from: http://www.ijponline.net/content/36/1/5

   Acid-Suppressant Medications by Belgian Pediatricians: Analysis of the National Database, [1997 –

   341: 495 - 498.

   University Press.


   Pump Inhibitors on Crying and Irritability in Infants: Systematic Review of Randomized Controlled


12. Information Services Division of NHS Scotland (ISD) (2016) Primary Care Workforce Survey Scotland
    Available on-line from: Available on-line from: http://www.isdscotland.org/Health-Topics/General-
    Practice/Publications/2016-06-14/2016-06-14-PrimaryCareWorkforceSurveyScotland2015-
    Summary.pdf


    Infants with Regurgitation? Pediatrics. 120: 946 - 949.

    Safety and Efficacy of Proton Pump Inhibitors in Paediatric Gastroesophageal Reflux Disease. Drug


