EIGHT different award types; INCREASED Junior Faculty FUNDING; NEW Health Equity Research Award; Med Resident and Student Awards

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Grant System Opens: September 7, 2021

Deadline: December 3, 2021

Read the Grant Flyer, FAQs, or visit the webpage for the full RFAs.

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Participating in the Webinar

All attendees will be muted and will remain in Listen Only Mode.

Type your questions here so that the moderator can see them. Not all questions will be answered but we will get to as many as possible.
How to Receive CME and MOC Points

LIVE VIRTUAL GRAND ROUNDS WEBINAR

ACG will send a link to a CME & MOC evaluation to all attendees on the live webinar.

ABIM Board Certified physicians need to complete their MOC activities by December 31, 2021 in order for the MOC points to count toward any MOC requirements that are due by the end of the year. No MOC credit may be awarded after March 1, 2022 for this activity.

MOC QUESTION

If you plan to claim MOC Points for this activity, you will be asked to: Please list specific changes you will make in your practice as a result of the information you received from this activity.

Include specific strategies or changes that you plan to implement.

THESE ANSWERS WILL BE REVIEWED.
ACG Virtual Grand Rounds

Join us for upcoming Virtual Grand Rounds!

Week 35, 2021
Getting Ready for Artificial Intelligence in Gastroenterology
Tyler M. Berzin, MD, FACP
September 9, 2021 at Noon Eastern

Week 36, 2021
ACG Clinical Guideline: Prevention, Diagnosis, and Treatment of Clostridioides difficile Infections
Colleen R. Kelly, MD, FACP
September 16, 2021 at Noon Eastern

Visit gi.org/ACGVGR to Register
COVID-19: Where Are We Now?
Updates from the ACG COVID-19 Task Force
MONDAY, SEPTEMBER 20th, 8 to 9:30 pm EDT

Introduction
- David A. Greenwald, MD, FACG

Speakers
- Harish K. Gagneja, MD, FACG
- Francis A. Farraye, MD, MSc, MACG
- Melissa Latore, MD, MS
- Samir Shah, MD, FACP
- Michael S. Morelli, MD, CPE, FACP

Co-hosts
- Costas H. Kefalas, MD, MMM, FACP
- Neil Stollman, MD, FACP

Register & Learn More: gi.org/ACGVGR

Disclosures:

Speaker:
William D. Chey, MD, FACP
Consultant: Phathom, Redhill, Takeda.

Moderator:
Grigoris I. Leontiadis, MD, PhD
Dr. Leontiadis, faculty for this educational event, has no relevant financial relationship(s) with ineligible companies to disclose.

*All of the relevant financial relationships listed for these individuals have been mitigated
The American College of Gastroenterology acknowledges educational grant support for this Virtual Grand Rounds webinar from:

RedHill Biopharma, Inc.

Management of Helicobacter pylori in 2021

William D. Chey, MD, FACG
Professor of Medicine
University of Michigan
Race/Ethnicity Prevalence

<table>
<thead>
<tr>
<th>Race/Ethnicity</th>
<th>Prevalence</th>
</tr>
</thead>
<tbody>
<tr>
<td>United States</td>
<td>35%</td>
</tr>
<tr>
<td>Caucasian</td>
<td>26%</td>
</tr>
<tr>
<td>African American</td>
<td>54%</td>
</tr>
<tr>
<td>Hispanic</td>
<td>60%</td>
</tr>
<tr>
<td>Alaska Native/Native American</td>
<td>75%</td>
</tr>
<tr>
<td>Elderly &gt;60 years</td>
<td>50%</td>
</tr>
<tr>
<td>Asian*</td>
<td>70%</td>
</tr>
</tbody>
</table>


H. pylori Clinical Consequences:

• Complications of untreated or undertreated H pylori:
  • Gastritis
  • Gastric and duodenal ulcers
  • Gastric cancer
  • Gastric mucosa-associated lymphoid tissue lymphoma

Long-term follow-up of 1000 pts with bleeding PUD after treatment of *H. pylori*

- 1000 pts with bleeding *Hp* PUD from Spain were prospectively followed for >12 months
- 75% male, 41% had hx of NSAID use
- 69% DU, 27% GU, 4 pyloric ulcer
- Recurrence of bleeding: 3 @ year 1, 2 @ year 2
- Cumulative incidence of rebleeding:
  - 0.5% (0.16-1.16%) or 0.15% per pt year of FU
- Conclusion: *Hp* eradication virtually eliminates the risk of ulcer rebleeding


ACG *H. pylori* guidelines: Indications

**Gastric MALT lymphoma**
- *H. pylori* plays a role in pathogenesis of some with MALT lymphoma
- *H. pylori* eradication achieves tumor regression in 60–90%

- **Low-grade MALT lymphoma**
  - 3–13% recurrence over 5 years

- **High grade MALT lymphoma**
  - Remission 64% with 0% recurrence in patients with complete remission. (5-year follow-up)

- *H. pylori* eradication is recommended in gastric MALT lymphoma

1Farinha et al, Gastroenterology 2005; 128: 1579
2Montalban et al, Expert Rev Anticancer Ther 2006; 6: 361
3Nakamura et al, Cancer 2005; 104: 532
4Chen et al, J Natl Cancer Inst 2005; 97: 1345
H. pylori Eradication to Prevent Sporadic Gastric Cancer


NNT with eradication therapy to prevent one gastric cancer[b] = 15 (Chinese men) → 245 (US women)

Other Indications for *H. pylori* Testing & Treating

- Uninvestigated dyspepsia
- Functional dyspepsia
- Aspirin or NSAIDs
- Unexplained iron deficiency
- Idiopathic thrombocytopenic purpura

*Chey et al. Am J Gastroenterol 2017;112:212*
Diagnostic Tests

Nonendoscopic
- Antibody detection
- Urea breath test
- Fecal antigen test

Endoscopic
- Rapid urease test
- Histology
- Culture/Molecular

Diagnostic Tests

Nonendoscopic
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Diagnostic Tests

Nonendoscopic
- Antibody detection
- Urea breath test
- Fecal antigen test

Endoscopic
- Rapid urease test
- Histology
- Culture/Molecular

Withhold PPI for 7-14 days before testing
Withhold bismuth and antibiotics 2-4 weeks before testing

Current US Treatment Paradigm for H. pylori

First Line
Triple Therapy

Salvage
Quadruple Therapy

Salvage
Levo Triple Therapy

Current US Treatment Paradigm for *H. pylori* 

First Line
Triple Therapy

→

Salvage
Quadruple Therapy

→

Salvage
Levo Triple Therapy


First-line *H. pylori* Therapies
First-line Therapies for *H. pylori*

<table>
<thead>
<tr>
<th>Regimen</th>
<th>Drugs (doses)</th>
<th>Dosing Frequency</th>
<th>Duration (Days)</th>
<th>FDA approval</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clarithromycin Triple</td>
<td>PPI (standard or double dose)</td>
<td>BID</td>
<td>14</td>
<td>Yes*</td>
</tr>
<tr>
<td></td>
<td>Clarithromycin (500 mg)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Amoxicillin (1 grm) or Metronidazole (500 mg TID)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bismuth Quadruple</td>
<td>PPI (standard dose)</td>
<td>BID</td>
<td>10-14</td>
<td>No**</td>
</tr>
<tr>
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<tr>
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<td></td>
</tr>
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</tr>
<tr>
<td></td>
<td>Amoxicillin (1 grm)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Nitroimidazole (500 mg)^*</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Chey et al. Am J Gastroenterol, 2017;112:212

WHO: Urgent Need for New Antibiotic Treatments

- February 2017 - WHO published a global priority pathogens list of antibiotic-resistant bacteria to help in prioritizing the R&D of new and effective antibiotic treatments
- The purpose was to identify the most important resistant bacteria at a global level for which there is an urgent need for new treatments
- Pathogens prioritized in 3 categories - Critical, High and Medium
- *H. pylori* (clarithromycin-resistant) was categorized as a pathogen for which there is a High Priority need to develop new treatments
H. pylori resistance over time:
Results of a meta-analysis

<table>
<thead>
<tr>
<th>Region</th>
<th>Year 1</th>
<th>Year 2</th>
<th>Year 3</th>
<th>Year 4</th>
<th>Year 5</th>
<th>Year 6</th>
<th>Year 7</th>
<th>Year 8</th>
<th>Year 9</th>
<th>Year 10</th>
</tr>
</thead>
</table>

178 studies, 66K isolates, 65 countries

Savoldi et al. Gastroenterol 2018;156:1372

H. pylori Antimicrobial Resistance in US

<table>
<thead>
<tr>
<th>Area</th>
<th>Year 1</th>
<th>Year 2</th>
<th>Year 3</th>
<th>Year 4</th>
<th>Year 5</th>
<th>Year 6</th>
<th>Year 7</th>
<th>Year 8</th>
<th>Year 9</th>
<th>Year 10</th>
</tr>
</thead>
<tbody>
<tr>
<td>Houston VA</td>
<td>347</td>
<td>135</td>
<td>800</td>
<td>345</td>
<td>189</td>
<td>381</td>
<td></td>
<td></td>
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<tr>
<td>Alaska</td>
<td>25</td>
<td>20</td>
<td>43</td>
<td>44</td>
<td>33</td>
<td>65.4</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Redhill US</td>
<td>13</td>
<td>16</td>
<td>30</td>
<td>17</td>
<td>30</td>
<td>21.8</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Multicenter</td>
<td>31</td>
<td>14</td>
<td>30</td>
<td></td>
<td></td>
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<tr>
<td>RI 2018-19</td>
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<td></td>
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<tr>
<td>Phathom Multicenter</td>
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<tr>
<td>2019-2021</td>
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</tr>
</tbody>
</table>


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### Previous Antibiotic Use and *H. pylori* Resistance

<table>
<thead>
<tr>
<th>Antibiotic course</th>
<th>Antibiotic sensitivity tested</th>
<th>0 courses</th>
<th>1 course</th>
<th>2+courses</th>
<th>RR</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quinolone</td>
<td>Levofloxacin</td>
<td>114 (4%)</td>
<td>7 (14%)</td>
<td>11 (27%)</td>
<td>1.8</td>
<td>1.24-2.49</td>
</tr>
<tr>
<td>Metronidazole</td>
<td>Metronidazole</td>
<td>114 (28%)</td>
<td>13 (38%)</td>
<td>5 (100%)</td>
<td>1.6</td>
<td>1.46-1.75</td>
</tr>
<tr>
<td>Clarithromycin</td>
<td>Clarithromycin</td>
<td>103 (7%)</td>
<td>21 (19%)</td>
<td>8 (25%)</td>
<td>1.5</td>
<td>0.92-2.41</td>
</tr>
<tr>
<td>Erythromycin</td>
<td>Clarithromycin</td>
<td>104 (8%)</td>
<td>15 (20%)</td>
<td>13 (15%)</td>
<td>1.1</td>
<td>0.82-1.59</td>
</tr>
</tbody>
</table>

RR is the ratio of the risk of being resistant per unit increase in number of courses.


---

### First-line Therapies for *H. pylori*

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*Chey et al. Am J Gastroenterol, 2017;112:212*
Meta-analysis of First-line *H. pylori* Therapies

Eradication Rates (%)

<table>
<thead>
<tr>
<th>Therapy</th>
<th>Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Triple 7</td>
<td>73</td>
</tr>
<tr>
<td>B-Quad 10-14</td>
<td>85</td>
</tr>
<tr>
<td>Concomitant 5-10</td>
<td>88</td>
</tr>
</tbody>
</table>

Li et al. BMJ 2015;351:h4052

Concomitant vs. Triple Therapy: A meta-analysis

- 23 RCTs including 3305 patients in the concomitant & 3327 in triple groups.
  - Overall, Concomitant therapy superior to triple therapy [RR: 1.15; 95% CI: 1.09–1.21; p < 0.001]
  - Significant heterogeneity ($I^2 = 74.0\%$, $p < 0.001$)
  - More AEs with Concomitant [RR: 1.2]
  - Subgroup analyses: Concomitant for 5- or 10-days superior to 7- or 10-day triple therapy
  - Concomitant may offer benefits for CI-R resistant Hp

Chen et al. Am J Gastroenterol 2018;113:1444
Other First-line Therapies

<table>
<thead>
<tr>
<th></th>
<th>Drug Combination</th>
<th>Treatment Schedule</th>
<th>Duration</th>
<th>Success Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Sequential</strong></td>
<td>PPI (standard dose) + Amoxicillin (1 grm)</td>
<td>BID</td>
<td>5-7</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td>PPI, Clarithromycin (500 mg) + Nitroimidazole (500 mg)</td>
<td>BID</td>
<td>5-7</td>
<td>No</td>
</tr>
<tr>
<td><strong>Hybrid</strong></td>
<td>PPI (standard dose) + Amox (1 grm)</td>
<td>BID</td>
<td>7</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td>PPI, Amox, Clarithromycin (500 mg), Nitroimidazole</td>
<td>BID</td>
<td>7</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td>(500 mg)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Levofloxacin Triple</strong></td>
<td>PPI (standard dose) + Levofloxacin (500 mg)</td>
<td>BID</td>
<td>10-14</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td>Amox (1 grm)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Levofloxacin Sequential</strong></td>
<td>PPI (standard or double dose) + Amox (1 grm)</td>
<td>BID</td>
<td>5-7</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td>PPI, Amox, Levofloxacin (500 mg QD), Nitroimidazole</td>
<td>BID</td>
<td>5-7</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td>(500 mg)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>LOAD</strong></td>
<td>Levofloxacin (250 mg)</td>
<td>QD</td>
<td>7-10</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td>PPI (double dose)</td>
<td>QD</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Nitazoxanide (500 mg)</td>
<td>BID</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Doxycycline (100 mg)</td>
<td>QD</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Chey et al. Am J Gastroenterol, 2017;112:212*

New developments since the 2017 ACG Guideline?

- FDA approval in 2019 of combination capsules containing omeprazole-rifabutin-amoxicillin
  - Indication: "treatment of *H pylori* infection in adults"

- Development & validation of potassium-competitive acid blocker (PCAB) based regimens
  - PCABs provide superior intragastric pH control compared to PPIs – enhancing antimicrobial efficacy and stability
  - Phase 3 RCT in US and Europe comparing 2 vonoprazan-based regimens with a PPI-based regimen[^a]

[^a]: a. ClinicalTrials.gov. NCT04167670.
Rifabutin-Based Triple Regimen (RHB-105) For *H pylori* Infection

- **Eradication rate**
  - Omeprazole + amoxicillin: 57.7%
  - RHB-105: 83.8%
- **Eradication rate in patients with confirmed adherence**
  - Omeprazole + amoxicillin: 64.7%
  - RHB-105: 90.3%

*P < .0001*

**Total daily doses in RHB-105 are:**
- Omeprazole 120 mg
- Amoxicillin 3000 mg
- Rifabutin 150 mg

**PCAB Mechanism of Action**

- Rapidly and reversibly inhibit the proton pump preventing acid secretion
- Greater elevation in intragastric pH than PPIs
- Dose-dependent effects on acid production
- Full effect after first dose

**Vonoprazan** accumulates in the acidic secretory canaliculus and non-covalently (reversibly) binds to proton pump with slow dissociation rate and can inhibit newly exposed proton pumps for extended periods.

Vonoprazan or PPI Triple Therapy for H. pylori: Impact of Clarithromycin Resistance

- Meta-analysis of 5 studies (2 RCTs) of vonoprazan vs PPI in triple therapy (n = 1599)

<table>
<thead>
<tr>
<th></th>
<th>OR</th>
<th>CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>CLA-susceptible (RCT)</td>
<td>1.6</td>
<td>(0.7, 3.6)</td>
</tr>
<tr>
<td>CLA-susceptible (non-RCT)</td>
<td>4.6</td>
<td>(0.7, 21.5)</td>
</tr>
<tr>
<td>CLA-resistant (RCT)</td>
<td>6.8</td>
<td>(3.6, 12.9)</td>
</tr>
<tr>
<td>CLA-resistant (non-RCT)</td>
<td>5.0</td>
<td>(2.5, 10.3)</td>
</tr>
</tbody>
</table>


Efficacy of Vonoprazan vs Lansoprazole Triple Therapy for H pylori Infection: Data from a US/Europe RCT

- Randomized, double-blind, controlled comparison of three 14-day regimens:
  - Vonoprazan 20 mg bid, amoxicillin 1 g bid, clarithromycin 500 mg bid
  - Vonoprazan 20 mg bid, amoxicillin 1 g tid
  - Lansoprazole 30 mg bid, amoxicillin 1 g bid, clarithromycin 500 mg bid

Modified ITT eradication rates (%) among patients without clarithromycin- or amoxicillin-resistant strains

Both vonoprazan-based regimens non-inferior to lansoprazole-based triple regimen
- P < .0001 for vonoprazan triple
- P = .0037 for vonoprazan dual

Phathom press release 4/29/21
**Treatment of *H. pylori*: Network Meta-Analysis**

*Take Home Point:* Vonoprazan triple therapy was the most effective and PPI triple therapy was the least effective

*Rokkas et al Gastroenterol 2021, online early*

---

**First Line *H. pylori* Therapy**

**Key Questions:**
1. Is there a penicillin allergy?
2. Has a macrolide antibiotic been taken in the past (for any reason)?

- **(-) Penicillin (-) Macrolide**
  - Treatments: Bismuth quadruple Concomitant Triple therapy Rifabutin triple Vonoprazan triple or dual

- **(-) Penicillin (+) Macrolide**
  - Treatments: Bismuth quadruple Rifabutin triple Vonoprazan triple or dual Levofloxacin Rx?

- **(+ Penicillin (-) Macrolide**
  - Treatments: Bismuth quadruple PCM

- **(+ Penicillin (+) Macrolide**
  - Treatment: Bismuth quadruple

*Chey et al. Am J Gastroenterol, 2017;112:212*
Post-Treatment H. pylori Testing

• Whenever H. pylori infection is identified and treated, testing to prove eradication should be performed using a urea breath test, fecal antigen test or biopsy-based testing at least 4 weeks after the completion of antibiotic therapy and after PPI therapy has been withheld for 1-2 weeks

• There may be infrequent situations which make eradication testing impractical or unnecessary

Chey et al. Am J Gastroenterol, 2017;112:212
Post-Therapy *H. pylori* Testing

- **Urea breath test**
  - Perform >4 wks after completion of therapy
  - May be accurate when done 2 weeks after therapy

- **Fecal antigen test**
  - Perform >4 wks after completion of therapy
  - Monoclonal test preferred

- **Biopsy-based testing**
  - histology ± RUT
  - requires multiple biopsies

Antibiotic Sensitivity Testing

- **Traditional Culture & Sensitivity**
  - Cumbersome
  - Technically challenging
  - Expensive
  - Not widely available

- **Molecular Testing**
  - fresh, frozen, paraffin embedded gastric bxs
  - PCR, fluorescently-labeled nucleic acid hybridization
  - Identify mutations associated with resistance to specific antibiotics
  - More scalable & less costly than culture & sensitivity

*Chey et al. Am J Gastroenterol, 2017;112:212*

*Nishizawa et al Front Mol Biosci 2014;1:19*
Antibiotic resistance after >2 failed Hp Treatments

- Amoxicillin: 2.27% resistance
- Ciprofloxacin: 50% resistance
- Clarithromycin: 79.6% resistance
- Metronidazole: 63.6% resistance
- Tetracycline: 2.27% resistance

![Graph showing antibiotic resistance percentages](Yang CGH 2015)

Salvage Therapy for Persistent or Recurrent *H. pylori* Infection
Salvage Therapy for \(H.\) pylori

- Do not use the same antibiotics
- Stress the importance of compliance and review possible side effects
- Treat for 10-14 days
- Use high dose PPI BID
- Consider culture and sensitivity testing after 2 failed attempts at empiric treatment

*Chey, et al. Am J Gastroenterol 2017;112:212
Song M, Ang TL World J Gastroenterol 2014;20(6): 1517*

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### Salvage Regimens for Persistent \(H.\) pylori

<table>
<thead>
<tr>
<th>Regimen</th>
<th>Drugs (doses)</th>
<th>Dosing Frequency</th>
<th>Duration (Days)</th>
<th>FDA approval</th>
</tr>
</thead>
</table>
| Bismuth Quadruple| PPI (standard dose)  
Bismuth subcitrate (120-300 mg) or subsalicylate (300 mg) 
Tetracycline (500 mg) 
Metronidazole (500 mg)  | BID or QID  
QID or QID | 14 | No** |
| Levofloxacin Triple | PPI (standard dose)  
Levofloxacin (500 mg)  
Amox (1 grm) | BID or QID  
QD or BID | 14 | No |
| Concomitant      | PPI (standard dose)  
Clarithromycin (500 mg)  
Amoxicillin (1 grm)  
Nitroimidazole (500 mg) | BID or QID  
BID or TID | 10-14 | No |
| Rifabutin triple | PPI (standard dose)  
Rifabutin (300 mg)  
Amox (1 grm) | BID or QID  
QD or BID | 10 | No |
| High-dose dual   | PPI (standard to double dose)  
Amox (1 grm TID or 750 mg QID) | TID or QID  
TID or QID | 14 | No |

*Chey et al. Am J Gastroenterol, 2017;112:212*
ACG Guideline Recommendations

- **Bismuth quadruple or levofloxacin salvage regimens** are the preferred treatment options if a patient received a first-line treatment containing clarithromycin.

- **Clarithromycin- or levofloxacin salvage regimens** are the preferred treatment options if a patient received first-line bismuth quadruple therapy.

- Selection of the best salvage regimen should be directed by local antimicrobial resistance data and the patient’s previous exposure to antibiotics

*Chey et al. Am J Gastroenterol, 2017;112:212*

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AGA Clinical Practice Update for Persistent *H pylori*

Flowchart showing treatment options and decision points based on antimicrobial resistance and previous exposure to antibiotics.

Take Home Points:

• Key factors to consider when choosing *primary therapy* for *Hp*:
  • PCN allergy?
  • Previous macrolide (or quinolone) exposure?
  • Quadruple therapies and novel triple and dual therapies are replacing traditional PPI triple therapy
    • Rifabutin triple and vonoprazan triple and dual regimens are exciting and effective new options

• Key Factors to consider when choosing *salvage therapy*:
  • Avoid drugs used previously
  • Treat for 14 days
  • Quadruple therapies and Levofloxacin therapies are preferred
  • HD PPI & Amoxicillin and Rifabutin Triple therapies are other considerations
  • Optomize PPI therapy, PCAB therapy in the future?

Questions?

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Moderator:
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