ISSN 1007-9327 (print)
ISSN 2219-2840 (online)

# World Journal of *Gastroenterology*

Weekly Volume 32 Number 40 October 28, 2026

Published by Baishideng Publishing Group Inc

# World Journal of

# *Gastroenterology*

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## 2026-2029

Published by **Baishideng Publishing Group Inc**
7041 Koll Center Parkway, Suite 160, Pleasanton, CA 94566, USA
https://www.wjgnet.com

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## ORIGINAL ARTICLE

### Case Control Study

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*World Journal of Gastroenterology*

**Weekly Volume 32 Number 40 October 28, 2026**

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Peer Review of *World Journal of Gastroenterology*, Payton Yau, PhD, Lecturer, Department of Biosciences, School of Science and Technology, Nottingham Trent University, Nottingham NG11 8NS, United Kingdom. payton.yau@ntu.ac.uk

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## INDEXING/ABSTRACTING

The *WJG* is now abstracted and indexed in Science Citation Index Expanded (SCIE), Scopus, *Reference Citation Analysis*. The 2026 edition of Journal Citation Reports® cites the 2025 journal impact factor (JIF) for *WJG* as 7.7; Quartile: Q1. The *WJG*'s CiteScore for 2025 is 8.3.

## RESPONSIBLE EDITORS FOR THIS ISSUE

**Production Editor:** *Jiao Xu*; **Production Department Director:** *Xiang Li*; **Cover Editor:** *Jia-Ru Fan.*

**NAME OF JOURNAL**
*World Journal of Gastroenterology*

**ISSN**
ISSN 1007-9327 (print) ISSN 2219-2840 (online)

**LAUNCH DATE**
October 1, 1995

**FREQUENCY**
Weekly

**EDITORS-IN-CHIEF**
Andrzej S Tarnawski

**EDITORIAL BOARD MEMBERS**
http://www.wjgnet.com/1007-9327/editorialboard.htm

**PUBLICATION DATE**
October 28, 2026

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World Journal of Gastroenterology

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*World J Gastroenterol* 2026 October 28; 32(40): 120001

DOI: 10.3748/wjg.120001

ISSN 1007-9327 (print) ISSN 2219-2840 (online)

OPINION REVIEW

# *Helicobacter pylori* retreatment: When clinical guidelines meet patient reality

Ze-Yan Ren, Li-Ping Liang, Ying Deng, Mu-Di Yang, Zhi-Qing Wang, Le Liu

**Peer review:** Externally peer reviewed.
**Peer-review model:** Single blind
**Peer-review report's classification**
**Scientific quality:** Grade A, Grade A, Grade B, Grade B, Grade B
**Novelty:** Grade A, Grade B, Grade B, Grade B, Grade B
**Creativity or innovation:** Grade A, Grade A, Grade B, Grade C, Grade C
**Scientific significance:** Grade A, Grade A, Grade A, Grade B, Grade B
**P-Reviewer:** Gong EJ, Associate Professor, MD, PhD, South Korea; Losurdo G, Associate Professor, MD, PhD, Italy; Özden Y, MD, Türkiye
**Received:** February 12, 2026
**Revised:** April 14, 2026
**Accepted:** June 2, 2026
**Published online:** October 28, 2026
**Processing time:** 214 Days and 13.2 Hours
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## Abstract

*Helicobacter pylori* eradication failure is often framed in terms of regimen performance and antimicrobial resistance. Real-world evidence, though, suggests that the clinical course after treatment failure warrants closer attention. Registry data indicate that some patients with confirmed persistent infection do not go on to receive rescue therapy. Resistance alone is unlikely to account for this gap. Other contributors may include treatment burden, prior intolerance, difficulty maintaining adherence, inconsistent risk communication, limited access to susceptibility testing, and fragmented follow-up. In this Opinion Review, recent developments of rescue therapy are discussed while emphasising that post-failure management should be considered as a care pathway rather than a prescribing event. We highlight unsolved questions regarding empirical *vs* susceptibility-guided retreatment, older patients, patient-centered communication, quality assessment after failure. More effective rescue regimens remain important but they will not fully address retreatment gap without structured reassessment, individual counselling, adhesion support, planned confirmation of eradication.

**Key Words:** *Helicobacter pylori*; Eradication failure; Rescue therapy; Retreatment; Adherence; Shared decision-making

**Core Tip:** The antimicrobial resistance is not the only cause of the gap in treatment after eradication failure. The variables, which are likely to be contributing to this situation, include treatment load, past ill effects, non-compliance and break-off, communication failure or miscommunication, or break-off of follow-up. Although better rescue regimens will be required, they will not fill this gap on their own. Failure should be followed by structured reassessment, patient specific counselling, and tangible follow up.

**Citation:** Ren ZY, Liang LP, Deng Y, Yang MD, Wang ZQ, Liu L. *Helicobacter pylori* retreatment: When clinical guidelines meet patient reality. *World J Gastroenterol* 2026; 32(40): 120001
**URL:** https://www.wjgnet.com/1007-9327/full/v32/i40/120001.htm
**DOI:** https://dx.doi.org/10.3748/wjg.120001

## INTRODUCTION

Infection by *Helicobacter pylori* (*H. pylori*) is one of the world's most common chronic bacterial infections. It continues to play a central role in the pathogenesis of peptic ulcer disease, chronic gastritis, premalignant gastric lesions, and gastric cancer[1,2]. A substantial body of mechanistic and epidemiologic evidence has established persistent *H. pylori* infection as a major driver of gastric carcinogenesis[3-6]. This relationship is now being refined by single-cell evidence showing that *H. pylori*-associated gastric tumorigenesis involves not only epithelial alterations, but also broader remodeling of stromal, myeloid, and intercellular signaling landscapes[7]. In response to this evidence, recent international guidelines have increasingly endorsed eradication of documented infection whenever treatment is appropriate and feasible[8,9]. Meanwhile, large collaborative efforts such as the European Registry on *H. pylori* management (Hp-EuReg) have provided valuable insight into how *H. pylori* infection is managed in routine clinical practice beyond the controlled setting of clinical trials[10,11]. Lately, besides an expansion of therapy indications, the other most important change in everyday practice is greater difficulty being faced in obtaining long-lasting eradication with empirical first-line therapy [12-14]. Antimicrobial resistance and poor adherence are causing traditional regimens to become less reliable in today's practice[15,16]. The key problem after eradication failure is not just choosing the next regimen but ensuring that patients can realistically enter, complete, and confirm rescue therapy.

## THE POST-FAILURE GAP AS A SPECIFIC CLINICAL ISSUE

The majority of *H. pylori* management focuses on selection of first line regimen, confirmation of eradication, slowly becoming more focused on antimicrobial resistance. However, the recent Hp-EuReg analysis by Cantú-Germano *et al*[17] redirects attention to a later and far less examined stage of care: The management of patients after eradication failure has already been confirmed. Of 6904 documented treatment failure European patient, 14% failed to receive re-treatment, about half of this was attributed to patients and slightly more than two-fifths to physicians[17]. Findings of the registry reveal a clinically relevant post-failure gap, but not a proof of why it did not do so. Patient-related or physician-related non-retreatments are useful for describing practice patterns, but motivations are likely different and incompletely captured. Therefore, the retreatment gap should be seen as a signal needing further investigation rather than as evidence of any one causal pathway. Failure to confirm eradication and failure to initiate rescue therapy are not the same clinical problem. The former embodies post-treatment assessment that is incomplete, while the latter represents a decision-making malfunction for an established persistent infection. The clinical significance of the differentiation is that dealing with the disease is now considered not just symptomatic control but also a way of long term gastric cancer prevention[18,19]. Such a rationale of prevention has been reaffirmed by data from randomized trials and population-based studies[20-23].

## RECENT PROGRESS IN RESCUE THERAPY

Rescue therapy for *H. pylori* infection has evolved considerably over the past decade. The optimized bismuth quadruple therapy is an essential option, especially when susceptibility testing is unavailable. Also, when prior use of an antibiotic does not negate a reasonable chance of benefit[8,9,13,24]. Rifabutin-containing regimens have also regained attention in refractory settings, largely because rifabutin resistance remains uncommon and their efficacy in later-line treatment appears acceptable in appropriately selected patients[25-28]. These developments are also complemented by innovations in acid suppression. Randomized trials and pooled analyses show that using either a vonoprazan-based dual regimen or a vonoprazan-based triple regimen can lead to high eradication rates and a relatively simple treatment structure[29-31]. Early real-world data likewise suggest that vonoprazan-based rescue strategies may retain clinical value even in patients

with previous eradication failure[32,33]. An increased emphasis on susceptibility-guided and genotype-guided retreatment is another development. Comparative studies and meta-analyses are increasingly supporting tailored therapy after treatment failure, especially in patients with high previous antibiotic exposure[34-36]. Nevertheless, translating this approach into practice is difficult. The availability of culture-based testing, molecular resistance assays and timely reporting varies significantly across healthcare systems[8,37,38]. As a result, empirical retreatment continues to predominate in many real-world settings[39-42].

## REAL-WORLD DETERMINANTS OF NON-RETREATMENT

The registry analysis provides an important entry point for understanding why rescue therapy is not consistently undertaken after documented eradication failure. Earlier nonadherence, treatment intolerance in prior courses, older age, and multiple prior failures were correlated with lower chances for retreatment[17]. These associations are consistent with the possibility that antimicrobial resistance alone does not fully account for the post-failure gap, although registry data cannot determine the causal contribution of each factor. They also raise the possibility that patient experience during earlier treatment courses may influence subsequent decisions. Evidence beyond Hp-EuReg supports this view. According to the studies conducted on the real world, a substantial amount of variation in regimen selection, incomplete follow-up and the gap between the ondemand guideline and everyday practice exists[40-43]. Patient understanding is likewise uneven. Several surveys done in various regions reported that there is a lack of knowledge about transmission, cancer risk, reinfection, and purpose of eradication[44-47]. Similar disparities have been seen among physicians, undermining consistent application of recommended care[43,48,49]. Although social-media and short-video platforms may broaden access to *H. pylori*-related information, the variable quality of content and the potential for misinformation limit their reliability as a foundation for clinical decision-making[50-52]. Taken together, these observations support the hypothesis that non-retreatment may be shaped by broader shortcomings in implementation, communication, and follow-up, although the relative contribution of each factor remains uncertain.

## MAJOR CONTROVERSIES IN POST-FAILURE MANAGEMENT

One of the major controversies related to post-failure management is whether every recorded eradication failure must always be followed by another treatment. The present recommendations continue to favour eradication, as far as feasible, in principle[8,9,25]. According to meta-analyses and data from long-term randomized clinical trials, successful eradication lowers gastric cancer risk[18,21]. Community-based screening and mass-eradication programs support a treatment based on prevention, not just the development of symptoms[20,23]. In clinical practice, however, the balance between benefit and burden is not uniform across patients. A patient with peptic ulcer disease, premalignant gastric lesions, or increased gastric cancer risk presents a very different clinical scenario from a frail older adult who has already undergone several unsuccessful treatment attempts and is unwilling to continue. A related area of debate concerns the place of empirical rescue therapy in relation to susceptibility-guided treatment. Current evidence strongly supports the rationale for personalized treatment after treatment failure[8,9,25,53]. Even so, a universal insistence on resistance testing may be inappropriate in settings where such testing is inaccessible, prohibitively expensive, or too slow to inform the next therapeutic decision. In routine clinical practice, the more clinically relevant question is therefore not whether susceptibility-guided therapy is preferable in principle, but under which circumstances its added value justifies the delay it may introduce. The influence of age and comorbidity on retreatment decisions remains similarly unsettled. In Hp-EuReg, older age was associated with physician-driven non-retreatment[17]. Although that association is clinically plausible, chronological age alone is an inadequate basis for retreatment decisions. Data from elderly cohorts and the geriatric prescribing literature indicate that eradication therapy remains feasible and generally well tolerated in selected older adults, provided that frailty, polypharmacy, drug-drug interactions, life expectancy, and individual goals of care are assessed explicitly[54-56].

A recurring question is whether repeated treatment failure should be viewed primarily as a microbiological issue or as one of the care delivery process. In practice, these two dimensions often overlap. Antimicrobial resistance remains a major cause of treatment failure, and current evidence continues to support the importance of resistance patterns and adequate acid suppression[9,25]. This clinical concern is further reflected in disease-specific settings such as gastrointestinal lymphomas, where a recent meta-analysis linked *H. pylori* antibiotic resistance to poorer treatment outcomes[57]. Mechanistic studies further suggest that efflux pump activity may interact with resistance-associated mutations, indicating that refractory infection is a dynamic process of resistance acquisition and maintenance rather than the consequence of isolated point mutations alone[58]. Newer salvage options, including rifabutin- and vonoprazan-based regimens, address part of this biological challenge[26,28,29,32,33,59]. At the same time, repeated failure is also shaped by events surrounding the prescription itself. Real-world studies and adherence-focused interventions suggest that regimen complexity, poor understanding of treatment, adverse events, and fragmented follow-up can all reduce the likelihood that rescue therapy will be initiated, completed, or formally confirmed[16,17,44]. Digital reminders and structured educational support may help reduce some of these barriers[60-62]. Refractory infection should therefore not be interpreted solely through the lens of antibiotic resistance. The measure of quality after treatment failure is also disputed. Traditionally, the quality of *H. pylori* care has been judged by eradication rates and, more recently, by completion of post-treatment test-of-cure; both remain essential measures[9]. However, real-world data suggest that these endpoints alone

are insufficient, because some patients with likely persistent infection may not proceed to further treatment after first-line therapy. In a large US cohort, only 11.1% of patients who received first-line therapy went on to second-line therapy, and the authors suggested that not all patients with eradication failure received subsequent treatment[63]. Similarly, European registry data showed that up to 14% of patients with confirmed eradication failure were not retreated[17]. A more informative quality framework should therefore evaluate the entire post-failure pathway, including the initiation of rescue, the completion of treatment, and confirmatory testing after rescue, rather than stopping at completion of first-line therapy[64].

## ADHERENCE, TOLERABILITY, AND RISK COMMUNICATION

Recent studies show that adherence is modifiable. Current evidence shows a clear instructive education for the patient and communication support improve treatment completion and may also improve eradication outcomes[65-68]. Digital reminders and education delivered through new media are also of interest, particularly when integrated into routine follow-up rather than offered as one-off interventions[60,66]. Adherence support, therefore, should not be viewed as an optional adjunct after treatment failure, but as an integral component of regimen planning from the outset. The patient perspective remains insufficiently captured in *H. pylori* research. In the study by Cantú-Germano *et al*[17], approximately half of the decisions not to proceed with retreatment were classified as patient-driven, yet the underlying reasons were not recorded[17]. This is a meaningful gap. Survey data from the United States, China, Japan, and Jordan suggest substantial variation in public understanding of *H. pylori* infection, gastric cancer risk, and the rationale for eradication [44-47]. The quality of online health information, health literacy, risk perception, personal beliefs and worries, and practical barriers to access and complete follow-up influence further communication and decision-making[46,50,69-73]. Without accounting for these factors, the label "patient refusal" is too imprecise to inform clinical decision-making (Table 1).

## PERSPECTIVE ON RESCUE THERAPY AS A STRUCTURED CARE PATHWAY

We propose viewing rescue therapy as part of a structured post-failure care pathway rather than as a decision about regimen selection alone. Once failure of eradication is established, an initial treatment course should be systematically reviewed, including the regimen used, treatment duration, pill burden, dosing complexity, interruptions, tolerability and timing of confirmatory testing. The most likely driver of failure should then be assessed as primarily biological, behavioural, or system-related, while recognising that these factors often overlap. Only then should the selection of the next rescue regimen be made. The management plan should include measures that support therapy completion, including anticipatory counselling, simple instructions, adverse-event planning and a pre-arranged confirmatory test (Table 2). This framework is intentionally practical. Its central message is that eradication failure is not purely a microbiological event. Patient experience and the delivery of care are also part of the shaping process. More effective rescue regimens are important, but they are unlikely to close the retreatment gap on their own when that gap is also driven by prior intolerance, incomplete understanding, and reduced willingness to undergo further therapy. Post-failure management should therefore be seen as a care process that patients can realistically accomplish, rather than as a single prescribing decision.

## POSSIBLE FUTURE DIRECTIONS

Several priorities follow from the current evidence base. Registry-based research needs to move beyond documenting whether rescue therapy was prescribed and instead capture why it was declined, including patient-reported reasons and standardized measures of treatment burden[17,71,72]. The existing surveys already have provided significant information about knowledge gaps, however, they do not specify how these knowledge gaps affect the choice made when the failure is confirmed[47,50]. It will also be important to conduct prospective studies of implementation of structured post-failure care packages that incorporate both regimen selection and adherence support, adverse-event guidance and prearranged follow-up[61,62,65-68]. Comparative studies should also define more clearly which patients and practice environments derive meaningful benefit from tailored therapy beyond eradication rates alone, especially in healthcare systems where access to susceptibility testing remains constrained[37,73,74]. More broadly, prevention-oriented programmes should not be judged solely by first-line eradication success. Their evaluation should extend across the full care pathway, incorporating indicators for confirmatory testing after treatment, follow-up after documented persistence, uptake of second-line or rescue therapy, and final eradication outcomes.

## LIMITATIONS OF CURRENT EVIDENCE

Current evidence base subject several important limitations. Registry studies can contribute to defining actual practice but they are limited to causally distinguishing the relationship of events from patterns that arise from clinical selection.

**Table 1 Key advances, unresolved controversies, and practical implications in post-failure *Helicobacter pylori* management**

| Field | Current advance | Remaining controversy | Practical implication |
|---|---|---|---|
| Treatment strategy | Rescue treatment has moved beyond legacy triple therapy and now includes optimized bismuth quadruple regimens, rifabutin-containing options, and vonoprazan-based regimens[8,9,14,30,33] | The point at which empiric rescue should give way to susceptibility-guided therapy remains uncertain[8,25,38] | Document previous antibiotic exposure carefully and avoid reusing combinations that are unlikely to remain effective |
| Resistance testing | Culture-based and molecular/genotypic resistance-guided approaches are increasingly supported by comparative studies and reflected in contemporary guidelines[8,34,35,73] | Access to testing remains uneven, and waiting for susceptibility data may delay retreatment in routine practice | Use tailored therapy when testing is available, but do not let lack of testing lead to therapeutic inertia |
| Older patients | Age alone is increasingly recognized as an imprecise surrogate for treatment capacity[17,54] | How best to weigh long-term preventive benefit against frailty, polypharmacy, and patient preference remains debated | Assess comorbidity, frailty, and goals of care directly rather than relying on chronological cut-offs |
| Adherence support | Reinforced instructions, reminder systems, and structured education can improve treatment completion and, in some settings, eradication outcomes[65-67] | These interventions remain underused and are rarely incorporated into rescue pathways | Treat adherence support as part of treatment planning rather than as an optional add-on after failure |
| Program evaluation | Test-of-cure is now widely recognized as essential, but structured tracking after confirmed treatment failure remains underdeveloped[8,9,17,40] | Most quality frameworks still stop short of evaluating what happens after confirmed failure | Include rescue initiation, treatment completion, and confirmatory testing after rescue in quality assessment |

**Table 2 Proposed structured pathway after confirmed *Helicobacter pylori* eradication failure**

| Steps | Clinical questions | Suggested action |
|---|---|---|
| Verify failure | Was the test-of-cure performed at the appropriate interval, and off acid suppression or other confounding medications where relevant? | Confirm persistent infection before modifying treatment |
| Review the prior treatment course | Which drugs were used, for how long, and with what degree of dosing complexity? Were there missed doses, interruptions, or clinically relevant adverse events? | Review the prior regimen, duration, adherence, interruptions, and adverse-event history in detail |
| Identify the main driver of failure | Is the failure most likely related to resistance, poor adherence, treatment intolerance, or gaps in follow-up? | Define the principal contributors to failure and use this assessment to guide the next step |
| Choose rescue therapy | What were the previous antibiotic exposures, what is known about local resistance patterns, and are there allergy constraints or access to susceptibility testing? | Select an empiric or susceptibility-guided regimen that avoids likely cross-resistance and is feasible for the patient |
| Anticipate tolerability issues and support completion | Which symptoms or adverse effects mattered most during prior treatment, and what practical barriers may compromise completion this time? | Provide clear written instructions, anticipatory guidance on adverse events, and practical support to improve treatment completion |
| Arrange follow-up in advance | When and how will eradication be reassessed, and who will contact the patient if follow-up is missed? | Schedule test-of-cure and follow-up before the patient leaves, ideally with reminder support |

Patients who do not receive retreatment might differ systematically in ways not captured in existing data, including reasons related to socioeconomic disadvantage, medication costs and transportation difficulties, competing medical conditions, and quality of previous counselling. The data that's available also provides little insight into clinician decision-making and rarely includes validated patient-reported outcomes. These limitations do not undermine the significance of the signal identified by Hp-EuReg. However, they do argue against turning the observed correlations into causal conclusions. Another limitation is a relative lack of implementation-focused research. Many comparative studies still focus on which regimen produces the highest eradication rate. But far fewer compare how patients are counselled, followed, re-engaged in care after treatment failure. Consequently, it appears that the literature is much further advanced in pharmacologic optimization than with respect to care delivery science. In the context of post-failure management, this imbalance is no longer trivial: A field that continues to refine rescue regimens while paying insufficient attention to the clinical pathway surrounding them may improve efficacy in theory more readily than effectiveness in routine practice.

## CONCLUSION

The management of *H. pylori* infection has progressed considerably, yet care after eradication failure remains far less standardized than first-line treatment. The retreatment gap highlighted by Cantú-Germano *et al*[17] is clinically important because it exposes a critical disconnect between guideline recommendations and real-world practice[17]. While antimicrobial resistance is important, non-retreatment may also be influenced by treatment burden, previous adverse experiences, adherence problems, risk communication, testing access and follow-up discontinuation. Therefore, failure

should be treated not only as need for another regimen, but as trigger for structured reassessment, counselling, adherence support and planned confirmation of eradication.

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## FOOTNOTES

**Specialty type:** Gastroenterology and hepatology

**Country of origin:** China

**Author contributions:** Ren ZY and Liang LP contributed equally to this work and should be regarded as co-first authors, who were involved in the literature review, construction of the review framework and drafting of the manuscript; Deng Y and Yang MD participated in literature retrieval and critical revision of the manuscript; Wang ZQ and Liu L contributed equally to the conception of the article, supervision of manuscript preparation and final approval of the version to be published, and should be regarded as co-corresponding authors, with Liu L taking responsibility for all contact and correspondence with the journal; and all authors have read and approved the final manuscript.

**AI contribution statement:** The authors used generative AI tools during the manuscript preparation to refine the language, improve readability, and ensure linguistic precision. It is important to note that all scholarly ideas, interpretations, and conclusions remain the sole intellectual contribution of the human authors.

**Supported by** the Guangdong Basic and Applied Basic Research Foundation, No. 2023A1515111183 and No. 2026A1515010582.

**Conflict-of-interest statement:** The authors declare no conflicts of interest.

**S-Editor:** Liu H
**L-Editor:** A
**P-Editor:** Zhao YQ

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