PEER REVIEW HISTORY

ARTICLE DETAILS

TITLE (PROVISIONAL)	A Multicenter Prospective Observational Study Protocol for Radiation Exposure from Gastrointestinal Fluoroscopic Procedures (REX-GI study)
AUTHORS	Nishida, Tsutomu; Hayashi, Shiro; Takenaka, Mamoru; Hosono, Makoto; Kogure, Hirofumi; Hasatani, Kenkei; Yamaguchi, Shinjiro; Maruyama, Hirotsugu; Doyama, Hisashi; Ihara, Hideyuki; Yoshio, Toshiyuki; Nagaike, Koji; Yamada, Takuya; Yakushijin, Takayuki; Takagi, Tadayuki; Tsumura, Hidetaka; Kurita, Akira; Asai, Satoshi; Ito, Yukiko; Kuwai, Toshio; Hori, Yasuki; Maetani, Iruru; Ikezawa, Kenji; Iwashita, Takuji; Matsumoto, Kengo; Inada, Masami

VERSION 1 – REVIEW

REVIEWER	Andrew England University of Salford, United Kingdom.
REVIEW RETURNED	26-Sep-2019

GENERAL COMMENTS	Thank you for the kind invitation to review the manuscript titled “A multicentre prospective observational study protocol for radiation exposure from gastrointestinal fluoroscopy procedures (REX-GI) study. General comments, 1. The author list was extensive, does this conform to the BMJ Open requirements? Did all authors make a reasonable intellectual contribution to the manuscript? 2. I think it needs to be made clearer throughout whether the focus was on diagnostic or therapeutic procedures (or a combination)? 3. There have been many survey type studies described within the literature which have the aim of helping produce DRL information. Why would a protocol, similar to studies which have been undertaken previously, be a useful addition to the literature? I note that this protocol as been registered with the relevant authorities. I do, however, believe that it is making a 'significant' new contribution to the literature. 4. The authors should confirm that there are no similar DRL studies available in Japan currently. 5. How did the authors deduce that the study would include data from recently launched fluoroscopy machines? Again, is this not currently available within the literature? The authors should take caution when making comments which could be perceived as highly subjective. 6. I think the statement that this study will be conducted in hospitals where gastroenterologists and endoscopists, who are concerned about medical radiation work, are based is a highly subjective statement. How do you know this for certain? Also, my guess is that you are not including all Japanese hospitals and

	does your result generate bias to those within an interest in medical radiation exposure – an not a general picture? Specific comments, 1. Can you truly establish DRLs for therapeutic procedures where the complex is likely to variable, sometimes considerably, on a patient-by-patient basis? 2. I would specifically like to know why you believe that a protocol publication would be useful to the readership and wider scientific community? 3. The study 'was' are 'will be' conducted. If it is past tense then why not simply report the findings, the methods statement will contain the protocol? 4. Setting and sample size – how do you know that you will recruit a sufficient number of cases to achieve an appropriate (statistically useful) sample size? This section needs greater justification. 5. Statistical analysis plan – how do you know how to treat the data until you have performed normality tests? Why are you not reporting mean (SD) values as opposed to median (IQR)? 6. I cannot see the value of simple linear regression in terms of FT and RD – are these relationships not already well accepted? 7. How will data collection take place? via online forms? Also, what steps are you taking to understand / check the reliability of the data. 8. What about quality assurance of the fluoroscopy equipment, what data will you collect on the characteristics of individual patients? 9. How will anonymised data be made available ? via a website? 10. Do you think you should have also considered peak skin dose within your work? 11. Table 2 – how will you record basic settings when these could change through the procedure? Also what about the geometry and location of the X-ray tube and image intensifier / IR? 12. I could see no evidence that you were collecting information about patient size. This would be crucial when establishing DRLs.

REVIEWER	Louise Rainford University College Dublin Ireland
REVIEW RETURNED	03-Nov-2019

GENERAL COMMENTS	I have considered the methodology and added comments based on experience regarding local and National DRLinvestigations. Abstract The focus needs to be on imaging equipment found in endoscopy units and this needs to be clear in the abstract and background introduction. The text claims there is limited text on RE for high dose medical imaging. This is not correct. The abstract needs to refer to literature published related to endoscopy suites to date. By bringing in other areas of imaging e.g. CV or hybrid vascular suites this is inappropriate. This similarly applies to the introduction section. It should be acknowledged that in Europe it is now mandatory through legislation that DRLs are known and recorded and how this varies across continents etc. As the study is prospective it is advisable that the complexity of a procedure is identified by the clinician to assist in the stratification

	of data cohorts. If this is prospective why is patient weight and BMI not being recorded? Methodology It needs to be clear if local and national DRLs are to be established. The issue of varying technology in imaging suites is noted in the Strengths & Limitations section. However, it needs to be clear in the methodology how this can be managed. For example, can the technology used RE imaging equipment be grouped to ID DRLs based on equipment available, this should be known at the start of the study. As a national study this is important as it may inform healthcare priorities if radiation dose levels are excessive in some sites with older technology. None of this is currently clear in the methodology. Further clarification is required as to what is meant by involving only centres were there is concern re radiation. A national study should include all studies and if they are not all included the percentage participating of the overall no. of sites needs to identified. It needs to be clear who will be making the observations and the training that is in place to ensure those responsible across sites are recoding data in a similar fashion. Background With respect to deterministic effects is there literature related to endoscopic suites? Is a serious concern as the text indicates it is and any literature supporting this concern for endoscopic suites should be included. If None exist this should be stated. Participating sites Greater detail is required about the participating sites with respect to equipment type and how the units will be grouped, the DRLs do need to take account of equipment. Also, the demographics of clinicians (operators should be collected). DRL references are required to justify sample sizes. General Points The grammar alternates from present tense to past therefore it is difficult to follow if the work has commenced or not.

VERSION 1 – AUTHOR RESPONSE

Reviewer #1's comments
Thank you very much for your valuable and constructive comments regarding our manuscript. We believe that the revised manuscript is significantly improved because of your comments. In the revised manuscript, we asked a copy editing company (American Journal Experts; http://www.aje.com/jp/) to correct the syntax errors.
Our responses to your comments are as follows:

General comments,
1. The author list was extensive, does this conform to the BMJ Open requirements? Did all authors make a reasonable intellectual contribution to the manuscript?
Response to comment #1: There is no description of a limit to the number of authors in the BMJ Author Hub. All authors discussed the protocol and recruited patients at each hospital. Therefore, we believe all authors have made a reasonable intellectual contribution to the manuscript.

2. I think it needs to be made clearer throughout whether the focus was on diagnostic or therapeutic procedures (or a combination)?
Response to comment #2: Thank you for your useful comment. To clarify whether the focus was on diagnostic or therapeutic procedures (or a combination), we have added the paragraph in the "Introduction" on page 10 in the revised manuscript (marked copy) as below.
Recently, various endoscopic procedures performed under fluoroscopic guidance are rapidly increasing in popularity in gastrointestinal endoscopy units, where the aim is not only diagnosis but also therapeutic intervention. The ICRP recommends that DRLs should be used to manage patient doses during both diagnostic and interventional procedures. There is difficulty in applying the DRL concept to interventional procedures because the RE level depends on the complexity of the procedure and the individual clinical circumstances 10 19 20. There have been attempts to establish DRLs for IVR procedures, where grouping by disease site may help minimize the wide distribution of RE 21 22.

3. There have been many survey type studies described within the literature which have the aim of helping produce DRL information. Why would a protocol, similar to studies which have been undertaken previously, be a useful addition to the literature? I note that this protocol as been registered with the relevant authorities. I do, however, believe that it is making a 'significant' new contribution to the literature.
Response to comment #3: As we commented above, to minimize the wide distribution of radiation exposure during interventional procedures, we are prospectively collecting data including disease site and procedure-related factors in each procedure; this is different from the previous surveys. To clarify this point, we have revised the last paragraph in the "Introduction" section as below in the revised manuscript.
The Japanese DRLs were established on a basis of a survey and released in 2015; these guidelines defined the DRL value for fluoroscopically guided interventional procedures as a fluoroscopic radiation dose rate (interventional reference point dose rate) of 20 mGy/min 12. However, it did not include information for specific procedures in the field of gastroenterology 12. Therefore, we aim to prospectively collect actual RE data and identify the influential factors, such as disease site, in this REX-GI study and to establish DRLs for the following interventional procedures in gastrointestinal endoscopy units: ERCP, interventional EUS, balloon-assisted enteroscopy, enteral metallic stent placement and enteral tube placement.

4. The authors should confirm that there are no similar DRL studies available in Japan currently.
Response to comment #4: Thank you for your comment. We have confirmed that there are no similar DRL studies available in Japan currently.

5. How did the authors deduce that the study would include data from recently launched fluoroscopy machines? Again, is this not currently available within the literature? The authors should take caution when making comments which could be perceived as highly subjective.
Response to comment #5: We have deleted this sentence. We have added Table 1 on Page 23 (marked copy), which shows the details of the fluoroscopic systems the in participating hospitals and revised the "Strengths and limitations of this study" section as follows:

These data may not be valid for old models of fluoroscopic systems because this study will include data from fluoroscopic systems with available radiation data.

6. I think the statement that this study will be conducted in hospitals where gastroenterologists and

endoscopists, who are concerned about medical radiation work, are based is a highly subjective statement. How do you know this for certain? Also, my guess is that you are not including all Japanese hospitals and does your result generate bias to those within an interest in medical radiation exposure – an not a general picture?
Response to comment: Thank you for your comment. We have deleted the related sentence in the "Strengths and limitations of this study" section.

Specific comments,
1. Can you truly establish DRLs for therapeutic procedures where the complex is likely to variable, sometimes considerably, on a patient-by-patient basis?
Response to comment #1: We agree with your comment that it is challenging to set DRLs for therapeutic interventions. We do believe that DRLs for therapeutic interventions are necessary because the distribution and high dose of therapy must be adequately controlled. To minimize the wide distribution of radiation, we are collecting data according to disease site for each procedure in the present study. German DRLs for endovascular aneurysm treatment were determined according to disease site (Strahlenschutz Bf. Bekanntmachung der aktualisierten diagnostischen Referenzwerte für diagnostische und interventionelle Röntgenanwendungen Vom 22. Juni 2016 [Available from: https://www.klinikum.uniheidelberg.de/fileadmin/strahlenschutz/linkimages/PDF/DRW-XRay-2016-07-15.pdf accessed Nov 9 2019. In addition, we reported the usefulness of the simple classification of ERCP according to disease site (Hayashi S, Nishida T, et al. Radiation exposure dose and influencing factors during endoscopic retrograde cholangiopancreatography. PloS one 2018;13(11):e0207539. doi: 10.1371/journal.pone.0207539). We think grouping by disease site is helpful to minimize the wide distribution of radiation dose during therapy. To explain that, we have added the following sentence on Page 10, line 268 in the revised manuscript (marked copy).

There have been attempts to establish DRLs for IVR procedures, where grouping by disease site may help minimize the wide distribution of RE 20, 21.

2. I would specifically like to know why you believe that a protocol publication would be useful to the readership and wider scientific community?
Response to comment #2: Our patient recruitment is planned for the period from May 2019 to December 2020. Subsequently, we will present the results at gastroenterology-, endoscopy-, or radiology-related congresses and published them in a peer-reviewed journal. However, we think it is essential to spread information about the concept of DRLs, including those based on disease sites, because of the low level of recognition of the DRL concept in the fields of gastroenterology and endoscopy. Therefore, we think a protocol publication would be useful for the broader scientific community.

3. The study 'was' are 'will be' conducted. If it is past tense then why not simply report the findings, the methods statement will contain the protocol?
Response to comment #3: We have revised this throughout the manuscript.

4. Setting and sample size – how do you know that you will recruit a sufficient number of cases to achieve an appropriate (statistically useful) sample size? This section needs greater justification.
Response to comment #4: Thank you for your comment. The ICRP 135 recommends using data from 20-30 facilities to set national DRLs, and a survey for a particular examination in a facility should usually involve the collection of data from at least 20 patients. Therefore, we did not determine upper limits, but we decided to include more than 20 facilities with 400 patients for each procedure in this

study. We have revised the “Setting the sample size” section.

The ICRP 135 recommends using data from 20-30 facilities to set national DRLs, and a survey for a particular examination in a facility should usually involve the collection of data from at least 20 patients 11.
To set the DRLs and to reduce intraprocedural variability in each hospital, we set the minimum sample size to at least 400 patients for each procedure.

5. Statistical analysis plan – how do you know how to treat the data until you have performed normality tests? Why are you not reporting mean (SD) values as opposed to median (IQR)?
Response to comment #5: Thank you for your advice. We have revised the “Data analysis plan” section as below on Page 15, line 400 (marked copy), in the revised manuscript.

After obtaining the data, we will perform normality tests. Continuous variables will be expressed as medians with interquartile ranges or means with standard deviations.

6. I cannot see the value of simple linear regression in terms of FT and RD – are these relationships not already well accepted?
Response to comment #6: A consensus regarding the simple linear regression between FT and RD has not been established. The American Society of Gastrointestinal Endoscopy (ASGE) recommends that the fluoroscopy time or radiation dose be measured (Gastrointest Endosc. 2015;81(1):54-66.). The Japan DRL 2015 set the IVR according to the radiation dose rate (mGy/min), which attempts to treat the wide distribution of interventional procedures based on the fundamental concept of the relation between RD and FT. Therefore, we followed the Japan DRL 2015 and plan to explore whether FT is a surrogate marker of RD in the field of gastroenterology and endoscopy. We have added the following explanation in the data analysis plan.

To explore surrogate markers of RD, simple linear regression analysis will be performed to identify the relationships between procedure time, FT and RD. A multiple linear regression analysis will be performed to identify the factors related to RD.

7. How will data collection take place? via online forms? Also, what steps are you taking to understand / check the reliability of the data.
Response to comment #7: We are collecting the password-protected case report forms by e-mail from each institution. These will be de-identified after all data have been collected, and all data queries have been addressed.
We have revised the “Data collection” section to include the above information.

8. What about quality assurance of the fluoroscopy equipment, what data will you collect on the characteristics of individual patients?
Response to comment #8: The quality of the fluoroscopy equipment is regularly monitored according to the practices in each hospital. We have added the following sentence about quality of the fluoroscopy equipment in the “Setting” section on page 13, line 348 in the revised manuscript (marked copy). Regarding the characteristics of the individual patients, we will collect age and sex (Table 2).

The quality of the fluoroscopic devices will be regularly monitored, according to the procedures in each institution.

9. How will anonymised data be made available ? via a website?
Response to comment #9: Individual participants and their clinical data will be identified by unique study identification numbers. We have added the following sentence to the “Data collection” section on page 16, line 435 in the revised manuscript.

A unique study identification number will identify each participant and the associated clinical data.

10. Do you think you should have also considered peak skin dose within your work?
Response to comment #10: Thank you for your suggestion. In the present study, we did not include the peak skin dose because DRLs do not always require this value.

11. Table 2 – how will you record basic settings when these could change through the procedure? Also what about the geometry and location of the X-ray tube and image intensifier / IR?
Response to comment #11: As you commented, the recorded setting is not always constant, particularly during interventional procedures. Therefore, we will collect the basic setting for each procedure. This is, however, an essential point, and we have added the following explanation to Table 2 in the revised manuscript. We also added Table 1 on Page 23 (marked copy) to show the fluoroscopic systems and units.

*When the setting changes during the procedure, we will record the basic setting data.

12. I could see no evidence that you were collecting information about patient size. This would be crucial when establishing DRLs.
Response to comment #12: Please see our response to specific comment #4.

Thank you very much. We believe that the revised manuscript is significantly improved because of your comments. We hope that the revised manuscript is acceptable for publication in BMJ Open.

Reviewer #2’s comments
Thank you very much for your valuable and constructive comments regarding our manuscript. We believe that the revised manuscript is significantly improved because of your comments. In the revised manuscript, we asked a copy-editing company (American Journal Experts; http://www.aje.com/jp/) to correct the syntax errors.
Our responses to your comments are as follows:

Abstract
#1. The focus needs to be on imaging equipment found in endoscopy units, and this needs to be clear in the abstract and background introduction. The text claims there is limited text on RE for high dose medical imaging. This is not correct.
Response to comment: Thank you for your useful comment. We have revised the abstract and background introduction to focus on imaging equipment in gastrointestinal endoscopy units.

#2. The abstract needs to refer to literature published related to endoscopy suites to date. By bringing in other areas of imaging e.g. CV or hybrid vascular suites this is inappropriate.
Response to comment: Thank you for your comment. We have amended the comparison with other areas of imaging and referred to publications regarding endoscopy units as below on page 8, line 195 (marked copy). We have referred to some papers published related to endoscopy units in the last

sentence of the second paragraph in the “Introduction” section.
There have been some reports on radiation-induced skin injury in cardiology and interventional radiology (IVR) 3, but reports from gastrointestinal endoscopy units are rare.

#3 This similarly applies to the introduction section. It should be acknowledged that in Europe, it is now mandatory through legislation that DRLs are known and recorded and how this varies across continents.
Response to comment: We have added the following sentences on page 9, line 229 (marked copy). Legislation has made it mandatory to establish and record DRLs in Europe, but that is not the case worldwide

#4. As the study is prospective, it is advisable that the complexity of a procedure is identified by the clinician to assist in the stratification of data cohorts. If this is prospective, why is patient weight and BMI not being recorded?
Response to comment: The ICRP 135 comments that there should be some standardization of weight for adult patients if data are collected from fewer than 50 patients. In this study, we set the minimum sample size to more than 200 patients for each procedure.

Methodology
#5. It needs to be clear if local and national DRLs are to be established. The issue of varying technology in imaging suites is noted in the Strengths & Limitations section.
Response to comment: We have added the following sentence to the Strengths & Limitations section.

Gastrointestinal fluoroscopic procedures have been rapidly increasing in number and complexity, but there are still not enough available local and national DRLs in gastrointestinal endoscopy units.

#6. However, it needs to be clear in the methodology how this can be managed. For example, can the technology used RE imaging equipment be grouped to ID DRLs based on equipment available, this should be known at the start of the study. As a national study this is important as it may inform healthcare priorities if radiation dose levels are excessive in some sites with older technology. None of this is currently clear in the methodology.
Response to comment: Thank you for your comment. At the start of the study, we examined the imaging equipment in each hospital. We will analyze the data based on the available equipment. We have added Table 1 on page 23 (marked copy), which includes this information. Unfortunately, it is difficult to include all hospitals because it is impossible to determine the radiation exposure from older fluoroscopic systems. We explained this bias as a limitation in the "Strengths and limitations of this study".

#7. Further clarification is required as to what is meant by involving only centres were there is concern re radiation. A national study should include all studies and if they are not all included the percentage participating of the overall no. of sites needs to identified. It needs to be clear who will be making the observations and the training that is in place to ensure those responsible across sites are recoding data in a similar fashion.
Response to comment: Thank you for your valuable comment. Unfortunately, this study is a prospective study designed to collect specific information related to procedures and not a survey. In addition, it is difficult to include all hospitals, as some cannot report the radiation exposure data due to the use of older fluoroscopic systems. We explained this bias as a limitation in the "Strengths and limitations of this study” as below.

These data may not be valid for old models of fluoroscopic systems because this study will include data from fluoroscopic systems with available radiation data.

Background
#8. With respect to deterministic effects is there literature related to endoscopic suites? Is a serious concern as the text indicates it is and any literature supporting this concern for endoscopic suites should be included. If None exist this should be stated.
Response to comment: We have added the following sentence in the Introduction on page 8, line 195 (marked copy).

There have been some reports on radiation-induced skin injury in cardiology and interventional radiology (IVR) 3, but reports from gastrointestinal endoscopy units are rare.

Participating sites
#9. Greater detail is required about the participating sites with respect to equipment type and how the units will be grouped, the DRLs do need to take account of equipment. Also, the demographics of clinicians (operators should be collected).
Response to comment: We have added Table 1 on page 23 (marked copy), which includes the information on the equipment type and units in the participating sites. We have added the following information to clinicians in the “Setting” section.

The participating physicians are gastroenterologists or endoscopists, including all experts and trainees working at all involved hospitals.

#10. DRL references are required to justify sample sizes.
Response to comment: Thank you for your comment. The ICRP 135 recommends using data from 20-30 facilities to set national DRLs, and a survey for a particular examination in a facility should usually involve the collection of data from at least 20 patients. Therefore, we did not determine upper limits, but we decided to include more than 20 facilities with 400 patients for each procedure in this study. We have revised the “Setting the sample size” section.

The ICRP 135 recommends using data from 20-30 facilities to set national DRLs, and a survey for a particular examination in a facility should usually involve the collection of data from at least 20 patients 11.
To set the DRLs and to reduce intraprocedural variability in each hospital, we set the minimum sample size to at least 400 patients for each procedure.

General Points
#11. The grammar alternates from present tense to past therefore it is difficult to follow if the work has commenced or not.
Response to comment: We have revised this.

Thank you very much. We believe that the revised manuscript is significantly improved because of your comments. We hope that the revised manuscript is acceptable for publication in BMJ Open.

VERSION 2 – REVIEW

REVIEWER	Andrew England University of Salford, United Kingdom.
REVIEW RETURNED	13-Dec-2019

GENERAL COMMENTS	My fundamental opinion on this manuscript remains unchanged. My main concern is two-fold, 1. This is a protocol, I am not sure of the unique value of publishing this - why not get on with the study and publish the methods and results together. I cannot see a rationale for presenting the protocol when there isn't sufficient novelty. Every author could make a case for a separate publication for the literature review, methods and then the results and discussion. Some may argue that this is salami slicing work and that it would only be warranted in unique / rare situations. I note that the study have been registered, is the protocol not available (or a summary) from the relevant website? If so, this would raise the question regarding duplication. 2. Determining DRLs require the assessment of patient size. I can see no evidence of this within the protocol. The authors failing to collect patient height and weight data is a big omission. Radiation dose is strongly correlated with these parameters. If they are to propose DRLs for Japan then there must be some certainty that the included patients are representative of the population. How would this be factored into DRL calculations (more data / info on how DRLs would be established could have been included within the manuscript). I did appreciate the comments regarding procedural severity and DRLs. If there was more focus on establishing this as a method, then I would be more positive. Since data collection is currently on-going any responses (letters to the editor) are unlikely to change the methods (the authors are loosing a benefit from the peer-reviewed journal process). I do, however, accept that the authors have made good attempt to comment on the issues that I have raised. I hope that my comments are useful. I would like to commend the authors on a well written manuscript. The reviewer provided a marked copy with additional comments. Please contact the publisher for full details. The reviewer completed the checklist but made no further comments.

VERSION 2 – AUTHOR RESPONSE

Reviewer #1's comments
Thank you very much for your valuable and constructive comments regarding our manuscript. Our responses to your comments are as follows:

1.This is a protocol, I am not sure of the unique value of publishing this - why not get on with the study and publish the methods and results together. I cannot see a rationale for presenting the protocol when there isn't sufficient novelty. Every author could make a case for a separate publication for the literature review, methods and then the results and discussion. Some may argue that this is salami slicing work and that it would only be warranted in unique / rare situations. I note that the study have

been registered, is the protocol not available (or a summary) from the relevant website? If so, this would raise the question regarding duplication.

Response to comment #1: Thank you for your comment. As stated in the author guidelines for BMJ Open (https://bmjopen.bmj.com/pages/authors/), publishing study protocols enables researchers and funding bodies to stay up to date in their fields by providing exposure to research activity that may not otherwise be widely publicized. This can help prevent unnecessary duplication of work and will hopefully enable collaboration. Publishing protocols in full also makes available more information than is currently required by trial registries and increases transparency, making it easier for others (editors, reviewers and readers) to see and understand any deviations from the protocol that occur during the conduct of the study. Our protocol manuscript adheres to this policy. Our present protocol was written in Japanese. Therefore, we believe that publishing this protocol in English is meaningful.

2. Determining DRLs require the assessment of patient size. I can see no evidence of this within the protocol. The authors failing to collect patient height and weight data is a big omission. Radiation dose is strongly correlated with these parameters. If they are to propose DRLs for Japan then there must be some certainty that the included patients are representative of the population. How would this be factored into DRL calculations (more data / info on how DRLs would be established could have been included within the manuscript).

Response to comment #2: Thank you for your comment. The ICRP 135 comments that there should be some standardization of weight for adult patients if data are collected from fewer than 50 patients. In this study, we set the minimum sample size to more than 400 patients for each procedure. In addition, in the present study, we included patients of a standard size for the Japanese population, whose weight ranged from 50 to 70 kg, as in other DRL surveys in the Japanese population. Therefore, we added the following sentence below Table 2 in the revised manuscript.

We will not collect patient weight or height because we will have selected patients of standard size for the Japanese population, whose weight will range from 50 to 70 kg.

Our co-author, Professor Makoto Hosono, has served as a member of the International Commission on Radiological Protection (ICRP) C3 since 2017. He has been contributed to fields such as radiation protection, neurology and cardiology. He also served as the Chief of the Working Group for the Establishment of National Diagnostic Reference Levels in 2015 (Japan DRLs 2015) and is now the Chair of the Japan Network for Research and Information on Medical Exposures (J-RIME). Unfortunately, as we described in the manuscript, there are still not enough available local and national DRLs in gastrointestinal endoscopy units, not only in Japan but also worldwide. We are conducting this study with him to serve as a basis for the development of DRLs in Japan.

In addition, during the review process, this research received clinical research grants from the Japanese Society of Gastroenterology. Therefore, we have updated the “Funding statement” section.

Thank you very much. We hope that the revised manuscript is acceptable for publication in BMJ Open.