



Identification of Physician Concerns Regarding Implementation of the Nagasaki Acute Myocardial Infarction Secondary Prevention Clinical Pathway

Masaya Kurobe, MD; Yosuke Yamanaka, MPH; Akihito Uda, PhD, MPH;
Katsuya Mori, PhD; Takeshi Akiyama, DBA; Ayumi Morishita, MPH;
Yuta Ishikawa, PhD, MPH; Louis P. Watanabe, PhD;
Satoshi Ikeda, MD, PhD, FJCS; Koji Maemura, MD, PhD, FJCS

Background: The Nagasaki Acute Myocardial Infarction Secondary Prevention Clinical Pathway (NASP) is a regional pathway that aims to standardize practices related to the treatment of acute myocardial infarction in order to improve patient prognoses. This study aimed to understand physician backgrounds and concerns regarding implementation of the NASP.

Methods and Results: This exploratory sequential mixed-methods study was developed around the RE-AIM (reach, effectiveness, adoption, implementation, and maintenance) framework. Following focus group interviews, the web-based, self-administered questionnaire survey with a cross-sectional study design was given to 62 physicians who practiced at acute care hospitals (ACHs), primary care hospitals (PCHs), or outpatient clinics (OCs) in the Nagasaki prefecture. Hayashi's quantitative theory type II analysis was used to assess the quantitative relationship between physician characteristics and their concerns. In addition, physicians were clustered based on the types of concerns they had. Our results demonstrated that specialists in cardiovascular disease held more concerns regarding implementation of the NASP. Furthermore, workload burden was found to be the most common concern among these physicians. Cooperation between physicians at ACHs and physicians at PCHs/OCs was also found to be vital for the NASP.

Conclusions: Interventions such as modifications to the NASP operation may assist in alleviating concerns regarding the NASP and allow for the development of tailored interventions and effective expansion of the pathway.

Key Words: Clinical pathway; Lipid management; Mixed methods; RE-AIM framework; Secondary prevention of acute myocardial infarction

Acute myocardial infarction (AMI), commonly known as heart attack, is a leading cause of mortality from cardiovascular events globally, including in Japan. Although the incidence of AMI in Japan has improved over the past few decades, recent trends also indicate that incidence of AMI have actually increased in the younger population.^{1,2} This, along with advances in clinical techniques, has led to a generally lower rate of mortality since 1995,¹ demonstrating the rising importance of secondary prevention. Moreover, therapeutic approaches for the management of cholesterol in patients with AMI varies widely by medical institute.^{3,4} Standardization of the treatment methods for patients suffering from AMI may improve the prognoses of patients and alleviate the

burden of decision-making for physicians.

Recently, a guideline-based regional clinical pathway, named the Nagasaki Acute Myocardial Infarction Secondary Prevention Clinical Pathway (NASP), was implemented in 8 foundation hospitals in Nagasaki, Japan. This pathway strives to maintain low-density lipoprotein (LDL)-cholesterol levels <70 mg/dL in patients who have experienced an AMI. It does so by offering standardized medical services at both acute care hospitals (ACHs) and primary care hospitals/outpatient clinics (PCHs/OCs). The effectiveness of the NASP has been demonstrated through improved achievement rates of LDL-cholesterol levels <70 mg/dL at discharge in a previous study.⁵ Further details about the NASP can be found in a previous study.⁶

Received October 9, 2024; accepted October 9, 2024; J-STAGE Advance Publication released online November 15, 2024 Time for primary review: 1 day

Department of Cardiovascular Medicine, Nagasaki University Graduate School of Biomedical Sciences, Nagasaki (M.K., K. Maemura); HEOR Group, Value and Access Division, Novartis Pharma K.K., Tokyo (Y.Y., A.U., K. Mori); Real World Evidence Solutions & HEOR, IQVIA Solutions Japan G.K., Tokyo (T.A., A.M., Y.I., L.P.W.); Stroke and Cardiovascular Diseases Support Center, Nagasaki University Hospital, Nagasaki (S.I.), Japan

K. Maemura is a member of *Circulation Reports* Editorial Team.

Mailing address: Koji Maemura, MD, PhD, FJCS, Department of Cardiovascular Medicine, Nagasaki University Graduate School of Biomedical Sciences, 1-7-1 Sakamoto, Nagasaki, Nagasaki 852-8501, Japan. email: maemura@nagasaki-u.ac.jp

All rights are reserved to the Japanese Circulation Society. For permissions, please email: cr@j-circ.or.jp

ISSN-2434-0790



The NASP is currently expanding to more healthcare facilities; however, further outreach to other hospitals and regions in Japan will require overcoming perceived barriers against the implementation of the NASP among healthcare providers (HCP) involved in the operation of the NASP.⁷ Previous studies have summarized the barriers against implementing a clinical pathway among clinicians, and grouped the barriers into individual, interpersonal, and institutional levels.^{8,9} In order to expand the NASP to new hospitals and regions, a tailored approach may be effective for overcoming the barriers perceived by physicians.¹⁰

The NASP will likely encounter both barriers that have been reported from previous clinical pathways and those that are unique to the NASP. In addition, the relationship between the characteristics of the physicians and these barriers remains unclear. Understanding the etiology of such physician concerns is vital for developing effective tailored interventions. Therefore, the objectives of this study were to identify the current concerns regarding the implementation of the NASP, to assess the associations between these concerns and physician characteristics using Hayashi's quantitative theory type II analysis, and to identify key physician characteristics for the development of tailored approaches by clustering physicians based on the types of concerns.

Methods

Study Design

This study was a non-interventional exploratory sequential mixed-methods design, beginning with a qualitative study phase followed by a quantitative study phase, following the RE-AIM (reach, effectiveness, adoption, implementation, and maintenance) framework.^{11,12} Prior to data collection, the study methodology was approved by an independent institutional review board, the Shiba Palace Clinic Institutional Review Board (Approval no. 152060_rn-34912). Prior to submission, this manuscript was reviewed by the Nagasaki University Graduate School of Biomedical Sciences Ethics Committee (Medical Course, Approval no. 23101301).

Overview of the Qualitative Study Phase

The focus group interviews were first conducted in person from December 2022 to February 2023 with 24 physicians who had experience treating patients with AMI in alignment with the NASP at foundation hospitals in Nagasaki city to collect key practices and barriers to the dissemination and operation of the NASP. The interview guide, described in a previous publication,⁶ was originally developed based on the RE-AIM framework, and was then independently reviewed by 3 cardiologists working at ACHs. The 1-h interviews were facilitated by researchers with experience in qualitative interviews, using a semi-structured interview guide developed based on the RE-AIM framework. After data collection from the interviews, 2 researchers with different academic backgrounds independently performed data coding and theme identification. Further details of the study methods for the qualitative study phase can be found in our previous publication.⁶ The identified themes and insights were applied to develop the original survey questions in Japanese (**Supplementary Appendix**; an English translation of the survey questions can be found in our previous publication).⁶ Following the interviews, the web-based, self-administered questionnaire survey was

implemented on a cross-sectional study design to quantify selected findings from the interviews. Details of the study methods for the quantitative survey are described in the paragraphs below.

Study Setting and Participants in the Quantitative Survey

Physicians who practiced at foundation hospitals or OCs in the Nagasaki prefecture and were willing to participate in the survey were considered eligible participants and invited to complete the study survey. Eligible participants were recruited in 2 ways: a non-probability convenient sampling approach, and a physician panel approach (**Supplementary Figure**). In the non-probability convenient sampling approach, representatives of the foundation hospitals and OCs in the Nagasaki prefecture were contacted by the researchers and asked to list potential participants with a medical specialty in cardiovascular disease (CVD) and/or with experience treating patients with AMI in alignment with the NASP. In addition, a physician panel was used to supplement recruitment of physicians practicing at PCHs/OCs in the Nagasaki prefecture. The recruitment of eligible participants and dissemination of the questionnaire were conducted using a physician panel owned and operated by Medical Tribune (<https://medical-tribune.co.jp/>). Medical Tribune, which provides survey services, has over 137,000 physicians registered as of October 2022. For the panel recruitment, an email was sent to all cardiologists registered to Medical Tribune as practicing in the Nagasaki prefecture. Consent was obtained from those who clicked the link and agreed to participate in the study. Participants were then asked to answer screening questions, and those who were eligible for the study were directed to the main questionnaire.

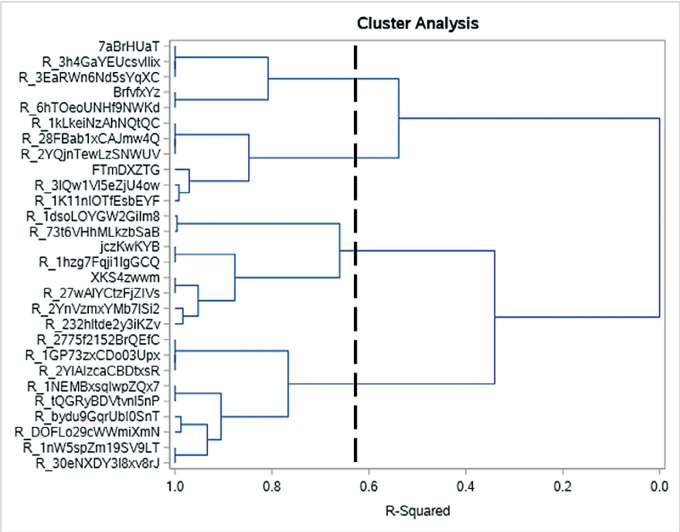
Data Collection in the Quantitative Survey

The original survey questions were developed through qualitative data integration of the focus group interviews with guidance from the RE-AIM framework. Prior to administration to the eligible participants, a pilot study was conducted among several CVD experts to ensure the validity of the survey question items and the constitution and cognition of the survey. The survey was implemented in June 2023 using different administration approaches, depending on the recruitment method. For the non-probability convenient samples, an online survey tool, Qualtrics® (Qualtrics, Provo UT), was used to design the questionnaire, and the questionnaire link was distributed to potential participants via email. For the physician panel, a questionnaire that was identical to the one described above, including wording of questions, answer formats, and survey logic, was developed and distributed to potential participants in the Nagasaki prefecture by Medical Tribune.

Statistical Analysis in the Quantitative Survey

Descriptive statistics were performed to summarize participant characteristics and participant-reported data, and participants were subgrouped based on whether or not they had concerns regarding the implementation of the NASP. All statistical tests were 2 sided, and P values <0.05 were considered statistically significant.

Hayashi's quantitative theory type II analysis, a multiple linear discriminant analysis of categorical data, was performed to assess the quantitative relationship between dependent and independent variables.^{13,14} Quantitative theory type II analysis calculates category scores, which



Number of Clusters	Pseudo F Statistic	Pseudo T-Squared
5	18.9	5.6
4	15.5	11.6
3	14.6	12.8
2	13.4	11.7

Figure 1. Dendrogram of the types of concerns regarding the implementation of the Nagasaki Acute Myocardial Infarction Secondary Prevention Clinical Pathway (NASP).

show the strength of association between a dependent variable and multiple independent variables, while considering other covariates. Larger categorical scores indicate a stronger association with a dependent variable. The quantitative theory type II model was developed based on correlation coefficients among participant characteristic and participant-reported data assessed using Cramer’s V statistic. An independent variable was selected into the model if a correlation coefficient with a dependent variable showed a very strong association, defined as Cramer’s V statistic of ≥ 0.25 .¹⁵ If a selected covariate was highly correlated with other selected covariates (Cramer’s V statistic ≥ 0.50), their Cramer’s V statistic values with a dependent variable were compared and the one with a higher Cramer’s V statistic value was included in the model to prevent a potential multicollinearity. In addition to categorical scores, the partial correlation coefficients and the ranges of category scores, defined as the difference between the maximum and minimum of the category scores for each independent variable, were calculated. A wider range of category scores indicates that the independent variable has greater influence on the dependent variable.¹⁶

Agglomerative hierarchical clustering analysis was performed using Ward’s method.¹⁷ This clustering method was selected as it is effective with smaller datasets, easy to understand visually through a dendrogram, and the ward method gives robust results by using the squared distance between all points and centroid.¹⁷ Three criteria were used to determine the optimal number of clusters: visual assessment of the dendrogram; pseudo F statistic, where a high value of the pseudo F statistic indicates an optimal number of clusters;¹⁸ and pseudo T-squared statistic, where a low value of the pseudo T-squared statistic indicates an optimal number of clusters.¹⁹ The results from the dendrogram, pseudo F statistic (18.9), and pseudo T-squared statistic (5.6) suggested using 5 clusters (**Figure 1**). However, if participants were clustered into 5 clusters, 1 cluster included only 2 participants, which is an insufficient number

of participants to identify the characteristics of the cluster. Therefore, the next suggested number of clusters of 4 was used in this study (pseudo F statistic 15.5; pseudo T-squared statistic 11.6). The differences in participant-reported data between the subgroups were examined using Fisher’s exact tests.

All statistical analyses were performed using SAS version 9.4 (SAS Institute) or R statistical software version 4.1.2 (R Foundation).

Results

Participant Characteristics

Participant demographic and clinical characteristics as well as participant reported data were subgrouped by those who had concerns for the implementation of the NASP at their medical institutes, and those who did not (**Tables 1,2**). The characteristics of the participants were similar in both the non-probability convenience sampling group and the physician panel group. The only differences were in the areas of medical specialty and experience with catheter intervention. This was expected, as the physician panel was intentionally composed of both cardiologists and non-cardiologists. Among the 62 participants, 28 (45.2%) had concerns, and 34 (54.8%) did not. In terms of the type of medical institute, most of the participants with concerns were those working at ACHs (89.3%). Conversely, those who were not concerned were at PCHs/OCs (67.7%). For ‘number of hospital beds’, the largest group of participants with concerns were those at hospitals with >400 hospital beds (42.9%), while those without concerns were at hospitals with <20 beds (44.1%).

Every participant who voiced a concern specialized in CVD (100%). The majority of those who were not concerned were in internal medicine with a specialty other than CVD (58.8%). Similarly, the vast majority of participants with ‘experience performing catheter interventions’ had concerns regarding implementation (96.4%), whereas those without

Table 1. Participant Characteristics From the Quantitative Study Phase			
	Total (n=62)	Concerned (n=28)	Not concerned (n=34)
Age (years)			
<30	5 (8.1)	3 (10.7)	2 (5.6)
30–39	17 (27.4)	10 (35.7)	7 (20.6)
40–49	15 (24.2)	3 (10.7)	12 (35.3)
50–59	13 (21.0)	7 (25.0)	6 (17.7)
≥60	12 (19.4)	5 (17.9)	7 (20.6)
Type of medical institute			
ACHs that accommodate AMI	36 (58.1)	25 (89.3)	11 (32.4)
PCHs/OCs that accommodate AMI	26 (41.9)	3 (10.7)	23 (67.7)
No. hospital beds at the medical institute			
≥400	18 (29.0)	12 (42.9)	6 (17.7)
200–399	11 (17.7)	8 (28.6)	7 (20.6)
20–199	15 (24.2)	5 (17.9)	6 (17.7)
<20	18 (29.0)	3 (10.7)	15 (44.1)
Medical specialty			
Cardiovascular	42 (67.7)	28 (100.0)	14 (41.2)
Internal medicine other than cardiovascular	20 (32.3)	0 (0.0)	20 (58.8)
Clinical experience (years)			
<10	13 (21.0)	8 (28.6)	5 (14.7)
10–19	17 (27.4)	6 (21.4)	11 (32.4)
20–29	16 (25.8)	7 (25.0)	9 (26.5)
≥30	16 (25.8)	7 (25.0)	9 (26.5)
Experience with catheter intervention			
Yes	48 (77.4)	27 (96.4)	21 (61.8)
No	14 (22.6)	1 (3.6)	13 (38.2)

Data are presented as n (%). ACH, acute care hospital; AMI, acute myocardial infarction; OC, outpatient clinic; PCH, primary care hospital.

Table 2. Participant-Reported Data From the Qualitative Study Phase			
	Total (n=62)	Concerned (n=28)	Not concerned (n=34)
Previously utilized another clinical pathway	32 (51.6)	16 (57.1)	16 (47.1)
The NASP is already implemented at my medical institute	42 (67.7)	24 (85.7)	18 (52.9)
Have sufficient clinical knowledge about lipid management for the secondary prevention of ACS			
Strongly agree	15 (24.2)	11 (39.3)	4 (11.8)
Agree	40 (64.5)	17 (60.7)	23 (67.7)
Disagree	7 (11.3)	0 (0.0)	7 (20.6)
Strongly disagree	0 (0.0)	0 (0.0)	0 (0.0)
Expertise required for understanding the NASP procedures			
Requires significant expertise (very difficult to understand)	1 (1.6)	1 (3.6)	0 (0.0)
Requires some expertise (somewhat difficult to understand)	10 (16.1)	4 (14.3)	6 (17.7)
Requires less expertise (less difficult to understand)	48 (77.4)	21 (75.0)	27 (79.4)
Requires no expertise (not difficult to understand)	3 (4.8)	2 (7.1)	1 (2.9)

Data are presented as n (%). Q1: Previously utilized another clinical pathway. Q5: The NASP is already implemented at my medical institute. Q7: Have sufficient clinical knowledge about lipid management for the secondary prevention of ACS. Q8: Expertise required for understanding the NASP procedures. ACS, acute coronary syndrome; NASP, Nagasaki Acute Myocardial Infarction Secondary Prevention Clinical Pathway.

experience typically did not (38.2%). Regarding lipid management, every participant who had concerns (100%) agreed with ‘having sufficient clinical knowledge about lipid management for the secondary prevention of acute coronary syndrome (ACS)’, whereas 20.6% disagreed with having sufficient knowledge. Last, 24 (85.7%) participants with concerns and 18 (52.9%) participants without concerns

reported that the NASP is already implemented at their medical institute.

Measuring the Correlation Between Concerns and Participant Demographics, Clinical, and Other Data

The correlation coefficients between the dependent (concerns) and independent variables (participant demo-



Figure 2. Correlation coefficients between participant characteristic and participant-reported data were calculated using Cramer's V statistic. Blue indicates a weak correlation, and red indicates a strong correlation. The magnitude is illustrated by color depth. ACS, acute coronary syndrome; NASP, Nagasaki Acute Myocardial Infarction Secondary Prevention Clinical Pathway.

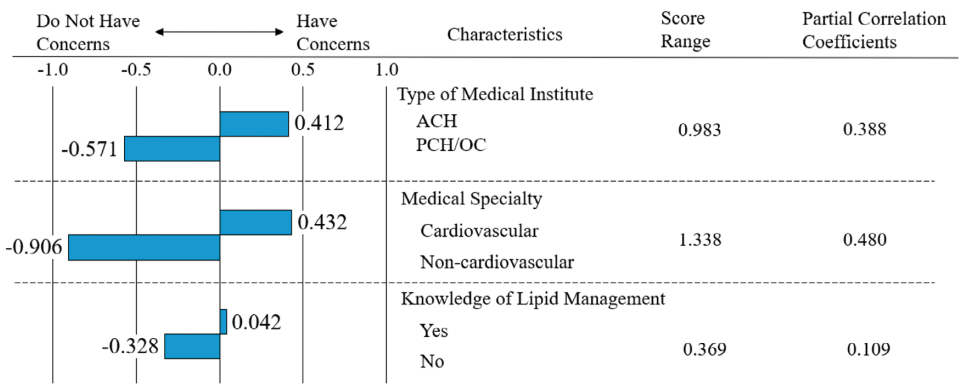


Figure 3. Physician backgrounds and their associations with concerns regarding the implementation of the NASP using Hayashi's Quantitative Theory Type 2. ACH, acute care hospital; NASP, Nagasaki Acute Myocardial Infarction Secondary Prevention Clinical Pathway; OC, outpatient clinic; PCH, primary care hospital.

graphic, clinical, and other reported data) are shown in **Figure 2**. Cramer's V was used to determine correlation (here in referred to as V). There was a strong correlation ($V \geq 0.250$) between the presence of concerns about the implementation of clinical pathways at the workplace for the following items: 'type of medical institution ($V=0.574$)', 'number of beds in the hospital ($V=0.395$)', 'medical specialty ($V=0.626$)', 'experience performing catheter interventions ($V=0.413$)', 'status of clinical pathway

implementation ($V=0.349$)', and 'knowledge about lipid management for the secondary prevention of ACS ($V=0.324$)'. There was also a strong correlation between the number of beds in the hospital and the type of medical institution exhibited a stronger correlation with the existence of concerns regarding the introduction of clinical pathways at the workplace than it did with the number of beds at the hospital. There was also a strong correlation between

Table 3. Types of Concerns for NASP Implementation	
Types of concerns for NASP implementation at my medical institute†	Concerned (n=28)
The level of agreement among physicians at the medical institute	15 (53.6)
The level of agreement among other HCPs at the medical institute	8 (28.6)
The environment at the medical institute (such as medications used)	4 (14.3)
The cooperation required between ACH physicians and PCH/OC physicians	16 (57.1)
Workload burden	18 (64.3)
Performance level	7 (25.0)
General concerns	0 (0.0)
Do not feel that the implementation of the NASP is effective	2 (7.1)

Data are presented as n (%). †Participants were allowed to select a maximum of 3 answer choices. Q11: Types of concerns for NASP implementation at my medical institute. HCP, healthcare provider. Other abbreviations as in Tables 1,2.

experience performing catheter interventions and medical specialty ($V=0.618$). Medical specialty also demonstrated an even stronger correlation with the presence of apprehensions concerning the implementation of a clinical pathway at the workplace. There was also a strong correlation between medical specialty and the status of clinical pathway implementation ($V=0.557$). Medical specialty indicated a stronger correlation with the existence of concerns regarding the introduction of clinical pathways at the workplace than with the status of clinical pathway implementation.

Hayashi's Quantitative Theory Type 2 Analysis

The results of the multivariate analysis using Hayashi's quantitative theory type 2 analysis, using 'the presence or absence of concerns about the implementation of the NASP at the workplace' as the dependent variable, are shown in **Figure 3**. Based on the results of the univariate correlation coefficients, the model incorporated the 'type of medical institution', 'medical specialty', and 'knowledge about lipid management for secondary prevention of ACS' as independent variables. The characteristics of physicians who expressed concerns about the implementation of the NASP at their workplace included 'working at an ACH that treats AMI' (category score=0.412, herein referred to as C), 'specializing in cardiovascular' ($C=0.432$), and 'possessing sufficient knowledge about lipid management for secondary prevention of ACS' ($C=0.042$). The variable that had the most influence on the presence or absence of concerns regarding the implementation of the NASP at the workplace was the 'medical specialty' variable (range=1.338; partial correlation coefficient=0.480).

Clustering the Participants Based on the Types of Concerns

Participants were clustered based on the types of concerns that they had (**Table 3**). The most prevalent concern was 'workload burden' at 64.3%, followed by 'the cooperation required between ACH physicians and PCH/OC physicians' (57.1%), and 'the level of agreement among physicians at the medical institute' (53.6%).

The number and frequencies of participants with each type of concern by cluster is shown in **Table 4**. Overall, the concerns that were significantly different across the clusters were 'the level of agreement among physicians at the medical institute' ($P<0.001$), 'the level of agreement among other HCPs at the medical institute' ($P<0.001$), 'the cooperation required between ACH physicians and

PCH/OC physicians' ($P=0.025$), and 'workload burden' ($P<0.001$). When clustering by frequently reported type of concerns, 4 clusters were generated and characterized. For Cluster 1, 100% of the participants had concerns for 'the level of agreement among physicians at the medical institute' and 'workload burden', and 50% had concerns for 'the cooperation required between ACH physicians and PCH/OC physicians'. Therefore, this cluster was designated as 'Dr. focused on physician concerns within the hospital'. For Cluster 2, 100% of the participants had concerns for 'workload burden' and 77.8% had concerns for 'the cooperation required between ACH physicians and PCH/OC physicians'. This cluster was designated as 'Dr. focused on physician concerns between hospitals'. In Cluster 3, 100% of the participants had concerns for 'the level of agreement among physicians at the medical institute' and 'the level of agreement among other HCPs at the medical institute', while 60% had concerns for 'workload burden'. This cluster was designated as 'Dr. focused on HCP concerns within the hospital'. Last, for Cluster 4, 75% had concerns for 'the cooperation required between ACH physicians and PCH/OC physicians' and 50% had concerns for 'the level of agreement among physicians at the medical institute'. Therefore, this cluster was designated as 'Dr. focused on HCP concerns between hospitals'.

Discussion

The present study on physician concerns regarding the implementation of the NASP revealed that almost half of the sampled participants harbored at least 1 reservation regarding the program's implementation. Notably, concerns were associated with the type of medical institute, physician medical specialty, and their clinical acumen in lipid management for the secondary prevention of ACS. Among these factors, medical specialty was the most significant determinant influencing apprehensions related to the NASP. Furthermore, through a cluster analysis, we categorized participants with reservations into 4 distinct groups. These insights provide a detailed landscape of the physician characteristics associated with concerns regarding the implementation of the NASP. Understanding these characteristics is vital for developing targeted interventions aimed at specific groups of physicians to address and mitigate their particular concerns, thereby fostering wider acceptance and successful integration of the NASP in clinical practice.

Table 4. Description of Participant Characteristics Based on Types of Concerns					
	Cluster 1	Cluster 2	Cluster 3	Cluster 4	P value
No. participants	6	9	5	8	
Cluster label	Dr. focused on physician concerns within the hospital	Dr. focused on physician concerns between hospitals	Dr. focused on HCP concerns within the hospital	Dr. focused on HCP concerns between hospitals	
Cluster characteristics	<ul style="list-style-type: none">• 100% had concerns about 'the level of agreement among physicians at the medical institute' and 'workload burden'• 50% had concerns about 'the cooperation required between ACH physicians and PCH/OC physicians'	<ul style="list-style-type: none">• 100% had concerns about 'workload burden'• 77.8% had concerns about 'the cooperation required between ACH physicians and PCH/OC physicians'	<ul style="list-style-type: none">• 100% had concerns about 'the level of agreement among physicians at the medical institute' and 'the level of agreement among other HCPs at the medical institute'• 60% had concerns about 'workload burden'	<ul style="list-style-type: none">• 75% had concerns about 'the cooperation required between ACH physicians and PCH/OC Physicians'• 50% had concerns about 'the level of agreement among physicians at the medical institute'	
Types of concerns about the implementation of the NASP at my medical institute					
The level of agreement among physicians at the medical institute	6 (100.0)	0 (0.0)	5 (100.0)	4 (50.0)	<0.001
The level of agreement among other HCPs at the medical institute	0 (0.0)	2 (22.2)	5 (100.0)	1 (12.5)	<0.001
The environment at the medical institute (such as medications used)	1 (16.7)	0 (0.0)	2 (40.0)	1 (12.5)	0.176
The cooperation required between ACH physicians and PCH/OC physicians	3 (50.0)	7 (77.8)	0 (0.0)	6 (75.0)	0.025
Workload burden	6 (100.0)	9 (100.0)	3 (60.0)	0 (0.0)	<0.001
Performance level	0 (0.0)	3 (33.3)	0 (0.0)	4 (50.0)	0.102
Do not feel that the implementation of the NASP is effective	1 (16.7)	1 (11.1)	0 (0.0)	0 (0.0)	0.810

Data are presented as n (%). P values were calculated using the Fisher's exact test. HCP, healthcare provider. Other abbreviations as in Tables 1,2.

Concerns Regarding the Collaboration Between Specialists in CVD and Primary Care Physicians

The results from this study indicated that physicians who specialized in cardiovascular medicine were more likely to have concerns regarding the implementation of the NASP. Moreover, one of the identified clusters from this study, ‘Dr. focused on physician concerns between hospitals’, had concerns regarding the cooperation required between ACH physicians and PCH/OC physicians. Specialists in CVD play a crucial role in managing patients with AMI by identifying high-risk cases. These cases may include patients with advanced coronary atherosclerosis, multivessel coronary artery disease, those undergoing lipid management who may require proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitors, or those with significantly reduced heart function due to heart failure. Specialists in CVD then decide whether these patients require more intensive treatment. However, cooperation between these specialists and primary care physicians is also crucial for long-term disease management of AMI, as patients often suffer from other comorbidities that must be managed together with AMI, and it is also important to provide frequent feedback on patients’ lifestyle habits. Therefore, it is important to have regular check-ups with primary care physicians who are readily available for addressing comorbidities and frailty to improve patient outcomes.

Another concern regarding collaboration may result

from primary care physicians about identifying and treating the adverse effects from high-intensity statins (the maximum dosage of a strong statin allowed per day). Revising the current NASP materials to incorporate a Q&A section for primary care physicians, focusing on prescribed medication and adverse events, may help to alleviate these concerns.

The NASP Requires Further Awareness and Agreement Between HCPs Within the Same Institute

Although the implementation of the NASP has been progressing since July 2022, it has also encountered some roadblocks. In particular, there is a NASP council that was formed by representatives with 100% participation from percutaneous coronary intervention implementation facilities in the city of Nagasaki, as well as some participation from prefectural and municipal medical associations in the Nagasaki prefecture. A point of discussion at a council meeting was that some physicians were not following the NASP for their treatment of AMI. These reports indicate that these physicians may be applying the original institutional protocol for certain procedures instead of the NASP. Moreover, there are also reports that even within the same institute, there are discrepancies in physicians following the NASP. Thus, it is possible that awareness of the NASP has not yet reached the appropriate threshold, even in institutes that have implemented the pathway. Generally, physicians gain competency with the NASP

through a NASP leader visiting their facility to explain the pathway. However, as this generally only occurs with key physicians, collaboration between the key physicians and other physicians and HCPs at the institute is necessary to raise awareness within the institute. Thus, increasing collaboration and the level of agreement between HCPs at the same institute may foster further discussion and lead to expanded usage of the NASP.

Previous studies have indicated that the successful application of clinical pathways can not only improve collaboration, but also show positive clinical outcomes.²⁰ Furthermore, initiatives such as conducting case study meetings for specific groups, providing feedback on the effectiveness of NASP, and regular updates on the usage rate of the NASP may stimulate cooperation from other physicians and HCPs, and aid in the development of multi-disciplinary teams (nurses, pharmacists, registered dietitians).

Workload Burden Was the Most Reported Concern for the Implementation of the NASP

The most reported concern by participants was that they believed that the implementation of the NASP would increase their workloads. Generally, standardizing clinical practices can mitigate concerns by potentially reducing workloads and treatment errors, as well as enhancing patient outcomes.^{7,21} However, certain NASP-specific interventions may be required to alleviate workload burden.

Currently, the NASP materials are included in the Okusuri-techo (Medication Notebook) in paper form, but as it is not necessary to present it to a primary care physician, this could lead to patients being more forgetful, resulting in additional work for the physician to fulfill the criteria of the NASP. In order to alleviate this issue, the Okusuri-techo could be replaced by the Ketsuatsu-techo (Blood Pressure Notebook, which must be brought to the physician), or all-inclusive materials could be developed for patients. Shinzo-byo-techo (Heart Health Diary), for example, is used to record treatment information for heart disease as well as blood pressure and weight, and must be presented to the primary care physician at each visit to share home blood pressure readings and other measurements. This type of system could reduce the chances of patients not bringing the appropriate materials for the NASP.

In addition, some participants from the focus group interviews pointed to prescribing PCSK9 inhibitors for AMI patients with LDL-cholesterol of ≥ 70 mg/dL even after prescribing high-intensity statins and ezetimibe as a disagreeable aspect of the NASP (data not shown). Therefore, it is possible that their concerns about workload burden stem from the administration procedure of PCSK9 inhibitors. Currently, training patients to use self-administered injectables is not consistent among physicians, with >40% stating that they do not train their patients.²² Moreover, there is a lack of standard practices for HCPs on the proper way to educate patients, especially since product labels fail to define what sufficient training entails. This situation may be contributing to the inconsistent training methods. The results from 1 ethnographic study revealed that while certain organizations adhere to comprehensive, self-devised training protocols and subsequent follow ups, others simply provide minimal training with little to no follow up.¹⁹ In addition, HCPs themselves may lack the capacity to adequately train patients despite their best intentions. Furthermore, HCPs might not have the

necessary resources to properly educate patients regardless of their intentions. Within today's healthcare setting, physicians are faced with reduced appointment durations for individual patients and a diminishing amount of direct interaction time.^{23,24} For example, the limitation of time has been identified as a major obstacle when conducting inhaler training at medical institutes, compelling physicians to place less emphasis on training to conserve time.²⁵ Therefore, it may be possible to ease the burden on physicians training their patients to use self-injectable PCSK9 inhibitors by promoting awareness campaigns on the training of self-injectables, or changing the outpatient environment.

Future Studies

The findings from this study can be leveraged for future studies. For example, the designated clusters can facilitate the provision of effective tailored interventions. Prediction models could be developed for the clusters using characteristics of physicians, such as medical specialty, years of clinical experience, and hospital size, allowing for a targeted understanding of the concerns that physicians may have when expanding the NASP to other prefectures and regions. The next step for the NASP should be to assess the key factors that lead to a successful intervention through the Consolidated Framework for Implementation Research (CFIR).²⁶ Last, this study identified both physicians who had concerns regarding the NASP, and those who did not. A study examining the differences in LDL-C <70 mg/dL achievement rates and prognoses between these 2 groups would provide insight into the real-world clinical impact of these concerns.

Study Limitations

This study has several limitations. First, other HCPs involved in the NASP, such as nurses and pharmacists, may have unique concerns that are different from those of the physicians surveyed. Second, the questionnaire was conducted during early phase implementation of the NASP, which may result in some bias with the responses. However, the statistical analysis approaches were considered to be robust for the sample size of this study. Allowing a physician the time to become more familiar with the pathway may also bring up different concerns, especially for non-cardiovascular specialists at PCH/OC. Third, there was limited external validity or generalizability of the study as the participants were recruited solely from the Nagasaki prefecture, meaning that the concerns from this study may be specific to the region. Fourth, despite our best efforts, the sample size was relatively small for a study examining the quality of clinical care. Last, only a small proportion of physicians who received the panel's invitation to the study agreed to participate. This may have led to bias in the answers and limited reproducibility of the study. Despite these limitations, this study provides valuable insights into the disease management of AMI and can contribute to improving patient quality of life.

Conclusions

This study aimed to identify physician concerns, and understand the etiology of these concerns regarding the implementation of the NASP in order to develop tailored solutions for continuing the expansion of the pathway. The key findings from this study are that participants with

expertise in CVD, along with those working at ACHs, had more concerns, and that workload burden was the most common concern. Understanding the types of physicians who have concerns enables targeting of physicians with certain backgrounds, while understanding the types of concerns allows for targeted interventions such as making changes to the NASP materials. Overall, this study offers greater insight into the implementation of the NASP, and also offers solutions to the problems that may hamper the future expansion of the pathway.

Acknowledgments

The authors express gratitude to all participants in this study.

Sources of Funding

This study was founded by Novartis Pharma K.K. Novartis Pharma K.K. has a specific role in the conceptualization and development of the study design, interpretation of data, decision to publish, and preparation of the manuscript. No honoraria or payments were made for authorship.

Disclosures

M.K. has received speaker honoraria from Novartis Pharma K.K. and Amgen K.K. S.I. has received speaker honoraria from Daiichi Sankyo Company, Ltd, Kowa Company, Ltd, Novartis Pharma K.K., Viartis Pharmaceuticals Japan Inc., and Bayer Yakuhin, Ltd. K. Maemura has received speaker honoraria from Daiichi Sankyo Company, Ltd, Novartis Pharma K.K., Takeda Pharmaceutical Company Ltd, Pfizer Japan Inc., MSD K.K., Bayer Yakuhin, Ltd, Kowa Company, Ltd, Amgen K.K., AstraZeneca K.K., and Viartis Pharmaceuticals Japan Inc. K. Maemura is a member of *Circulation Reports* Editorial Team. Y.Y., A.U., and K. Mori are employees of Novartis Pharma K.K. T.A., A.M., Y.I., and L.P.W. declare that they have no conflicts of interest.

Author Contributions

M.K., S.I., K. Maemura, Y.Y., A.U., and K. Mori were involved in the conceptualization of this study. M.K., K. Maemura, T.A., A.M., Y.I., and L.P.W. collected and analyzed qualitative and quantitative data and drafted the manuscript. All authors contributed to interpretation of the analyzed data, substantively revised the manuscript, and approved the final version of the manuscript.

IRB Information

Shiba Palace Clinic Institutional Review Board (Approval no. 152060_rn-34912). Nagasaki University Graduate School of Biomedical Sciences Ethics Committee (Medical Course, Approval no. 23101301).

Data Availability

The deidentified participant data will not be shared.

References

- Cui Y, Hao K, Takahashi J, Miyata S, Shindo T, Nishimiya K, et al. Age-specific trends in the incidence and in-hospital mortality of acute myocardial infarction over 30 years in Japan: Report from the Miyagi AMI Registry Study. *Circ J* 2017; **81**: 520–528.
- Yamamoto T, Yoshida N, Takayama M. Temporal trends in acute myocardial infarction incidence and mortality between 2006 and 2016 in Tokyo: Report from the Tokyo CCU Network. *Circ J* 2019; **83**: 1405–1409.
- Sawayama Y, Takashima N, Harada A, Yano Y, Yamamoto T, Higo Y, et al. Incidence and in-hospital mortality of acute myocardial infarction: A report from a population-based registry in Japan. *J Atheroscler Thromb* 2023; **30**: 1407–1419.
- Watanabe H, Morimoto T, Yamamoto K, Obayashi Y, Natsuaki M, Yamaji K, et al. Prevalence and effects of high-intensity statins for Japanese patients presenting with acute coronary syndrome: A post hoc secondary analysis of STOPDAPT-2 ACS. *Circ J* 2023; **87**: 657–668.
- Kurobe M, Baba K, Nunohiro T, Ishizaki M, Furudono S, Nakata T, et al. Impact of implementation of a region-wide low-density lipoprotein cholesterol management clinical pathway for the secondary prevention of acute myocardial infarction. *Circ J* 2024; **88**: 1825–1832, doi:10.1253/circj.CJ-24-0338.
- Kurobe M, Yamanaka Y, Uda A, Mori K, Akiyama T, Morishita A, et al. An evaluation of the best practices and barriers for the Nagasaki acute myocardial infarction secondary prevention clinical pathway. *J Med Econ* 2024; **27**: 1134–1145.
- Every NR, Hochman J, Becker R, Kopecky S, Cannon CP. Critical pathways. *Circulation* 2000; **101**: 461–465.
- Cabana MD, Rand CS, Powe NR, Wu AW, Wilson MH, Abboud PA, et al. Why don't physicians follow clinical practice guidelines?: A framework for improvement. *JAMA* 1999; **282**: 1458–1465.
- Evans-Lacko S, Jarrett M, McCrone P, Thornicroft G. Facilitators and barriers to implementing clinical care pathways. *BMC Health Serv Res* 2010; **10**: 182.
- Baker R, Camosso-Steinovic J, Gillies C, Shaw EJ, Cheater F, Flottorp S, et al. Tailored interventions to overcome identified barriers to change: Effects on professional practice and health care outcomes. *Cochrane Database Syst Rev* 2010; **17**: CD005470.
- Schoonenboom J, Johnson RB. How to construct a mixed methods research design. *Kolner Z Soz Sozpsychol* 2017; **69**: 107–131.
- Glasgow RE, Vogt TM, Boles SM. Evaluating the public health impact of health promotion interventions: The RE-AIM framework. *Am J Public Health* 1999; **89**: 1322–1327.
- Hayashi C. On the prediction of phenomena from qualitative data and the quantification of qualitative data from the mathematico-statistical point of view. *Ann Inst Stat Math* 1951; **3**: 69–98.
- Tanaka Y. Review of the methods of quantification. *EHP* 1979; **32**: 113–123.
- Akdoglu H. User's guide to correlation coefficients. *Turk J Emerg Med* 2018; **18**: 91–93.
- Matsuba T, Ding C, Lu L, Chiba Y. The utility of Hayashi's quantification theory type 2 for the rapid assessment of the epidemiological survey in the developing countries: In a case of the vaccine coverage survey in Yunnan Province, China. *J Epidemiol* 1998; **8**: 24–27.
- Gao CX, Dwyer D, Zhu Y, Smith CL, Du L, Filia KM, et al. An overview of clustering methods with guidelines for application in mental health research. *Psychiatry Res* 2023; **327**: 115265.
- Caliński T, Harabasz J. A dendrite method for cluster analysis. *Commun Stat* 1974; **3**: 1–27.
- Duda RO, Hart PE. Pattern classification and scene analysis. New York: Wiley, 1974.
- Herawati F, Irawati AD, Viani E, Sugianto NA, Rahmatin NL, Artika MP, et al. Effective clinical pathway improves interprofessional collaboration and reduces antibiotics prophylaxis use in orthopedic surgery in hospitals in Indonesia. *Antibiotics (Basel)* 2022; **11**: 399.
- Pearson SD, Goulart-Fisher D, Lee TH. Critical pathways as a strategy for improving care: Problems and potential. *Ann Intern Med* 1995; **123**: 941–948.
- Lang VA, Nalan D, editors. Combination product patient training: How are patients trained and who conducts the training? In: 2018 Design of Medical Devices Conference. American Society of Mechanical Engineers, 2018; V001T09A003–V001T09A003.
- Tai-Seale M, McGuire TG, Zhang W. Time allocation in primary care office visits. *Health Serv Res* 2007; **42**: 1871–1894.
- Young RA, Burge SK, Kumar KA, Wilson JM, Ortiz DF. A time-motion study of primary care physicians' work in the electronic health record era. *Fam Med* 2018; **50**: 91–99.
- Leung J, Bhutani M, Leigh R, Pelletier D, Good C, Sin DD. Empowering family physicians to impart proper inhaler teaching to patients with chronic obstructive pulmonary disease and asthma. *Can Respir J* 2015; **22**: 266–270.
- Damschroder LJ, Aron DC, Keith RE, Kirsh SR, Alexander JA, Lowery JC. Fostering implementation of health services research findings into practice: A consolidated framework for advancing implementation science. *Implement Sci* 2009; **4**: 50.

Supplementary Files

Please find supplementary file(s):
<https://doi.org/10.1253/circrep.CR-24-0124>