

厚生労働科学研究費補助金

がん対策推進総合研究事業

がんゲノム医療推進に向けたがん遺伝子パネル検査の実態把握と
がんゲノム医療提供体制構築に資する研究

令和5～7年度 総合研究報告書

研究代表者 内藤 陽一

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目 次

I． 総合研究報告書

がんゲノム医療推進に向けたがん遺伝子パネル検査の実態把握と がんゲノム医療提供体制構築に資する研究 内藤 陽一	----- 1
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II． 研究成果の刊行に関する一覧表	----- 10
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がんゲノム医療提供体制構築に資する研究

【研究代表者】内藤 陽一 国立研究開発法人国立がん研究センター 東病院 総合内科長

研究要旨

がんゲノムプロファイリング検査（CGP 検査）の課題である、①適合薬剤到達率が低いことと地域間差、②エキスパートパネル（EP）実施や臨床情報入力に関わる業務負担、③ゲノム医療従事者の人材育成等に対応するために、全国の EP においてアンケート調査を実施し、CGP 検査の実情について、薬剤到達率、地域差、EP における業務負担等を調査した。全国のがんゲノム医療中核拠点病院・拠点病院の代表者からなるアカデミア・アセンブリを組織し、EP における情報共有と、EDC を構築し臨床試験情報の共有を開始した。将来的な AI 等を活用した EP 実施のための医療機器開発を支援できる体制を構築するためのレジストリー研究を開始した。また、がんゲノム医療コーディネーター（CGMC）研修のための資料作成を行った。

令和7年度は、経時的変化の確認のために再度アンケート調査を実施する。また、アンケート調査結果等から政策提言を作成、また、アカデミア・アセンブリにおいて情報共有を継続しつつ、臨床試験情報共有を継続する。さらに、CGMC 研修のための資料更新を行う。

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A. 研究目的

がんゲノムプロファイリング検査（CGP 検査）が保険診療下で行われているが、①低い適合薬剤到達率と地域間差、②エキスパートパネル（EP）実施や臨床情報入力に関わる業務負担、③ゲノム医療従事者の人材育成等の課題を有する。

B. 研究方法

本研究では、(1) 中核拠点・拠点病院での適合薬剤到達率・地域間差、遺伝カウンセリング実施状況等の調査(担当：内藤、角南、今井、小山、吉野)、
(2) 薬剤到達率向上を目指したオンタイムでの治

験情報共有システム構築およびAI等を活用したEPおよびデータ入力の効率化(担当：内藤、角南、今井、小山、吉野)、(3) 抽出した課題と改善効果に基づく整備指針改訂に向けた提言書の作成(担当：内藤、角南、今井、小山、吉野)、(4) 医療従事者向け教育研修プログラムの作成(担当：内藤、角南、今井、小山、吉野)の4つの柱について、年次計画に基づいて実施する。これらの4つの柱は、相互に関連しており、シームレスな連携のもとに研究を遂行する。

(1) は、患者背景、薬剤到達率とその内訳（保険診療下での治療、治験参加、保険適用外での治療等）、遺伝カウンセリング実施の有無、EPの業務量等のデータ収集を行う。対象施設は中核拠点・拠点病院に加え、連携病院を可能な限り加えて実施し、施設間・地域間差も明らかにする。

(2) は、中核拠点病院・拠点病院の実務担当者からなる「アカデミア・アセンブリ」を構築する。そのうえで治験情報等の共有システムを構築し、実施上の課題抽出と克服、アカデミア・アセンブリにおいてAI等を活用したEP実施の医療機器開発に資するためのレジストリー研究を実施し、EPの省力化・自動化を目指したAI企業等との共同研究

を公募で決定し、研究を開始する。

(3) については、(1)の調査や(2)のアカデミア・アセンブリ構築などから、提言作成に必要な情報の収集や解析を行う。

(4) は、がんゲノム医療コーディネーター(CGMC)研修のためのカリキュラムや教育資材の作成を行う。作成したカリキュラム、教育資材を各中核拠点病院に提供してCGMC研修に活用を依頼する。

(倫理面への配慮)

レジストリー研究について研究計画書、説明同意文書を作成し、患者参画委員会の意見も拝受した。国立がん研究センター研究倫理審査委員会に諮問し承認を得た。研究実施にあたっては、関連法規や人を対象とする生命科学・医学系研究に関する倫理指針を遵守して行う。研究の実施にあたっては、倫理審査委員会で承認の得られた説明同意文書を研究対象者に渡し、文書及び口頭による十分な説明を行い、研究対象者の自由意思による同意を文書で取得する。

C. 研究結果

(1) 中核拠点・拠点病院での適合治療実施率・地域間差、遺伝カウンセリング実施状況等の調査を行った(担当：内藤、角南、今井、小山、吉野)。

2025 年実施のアンケート調査では、がんゲノム医療中核拠点病院（以下中核拠点病院）、がんゲノム医療拠点病院（以下拠点病院）、がんゲノム医療連携病院（以下連携病院）の 57 施設から回答が得られ、2024 年 7 月 1 日～2025 年 6 月 30 日の 1 年間に実施されたエキスパートパネル（EP）での検討症例数は 23,384 例、うち自施設例 12,152 例（52.0%）であった。自施設の症例（12,152 例）に対して、治療提案割合 43.9%、治療到達率 8.0%、うち企業治験 1.0%、NCCN1901（受け皿試験）0.3%、保険診療 6.3%、保険適用外使用 <0.1% であった。2024 年に実施したアンケートと比較して、治療到達率はわずかではあるが統計学的に有意に増加した(p=0.0029、表)。アカデミア・アセンブリを組織し、治験情報の共有のシステム構築から 1 年経過し、わずかな改善につながった可能性が示唆される。遺伝カウンセリング外来受診は 10.8%であった。

表 治療到達率の推移

期間	2022 年 7 月 ～ 2023 年 6 月	2023 年 7 月 ～ 2024 年 6 月	2024 年 7 月 ～ 2025 年 6 月
調査対象	中核拠点 13 施設、拠点 32 施設	中核拠点 13 施設、拠点 30 施設、連携 14 施設	中核拠点 13 施設、拠点 29 施設、連携 15 施設

CGP 件数	19,593	22,554	23,384
治療到達割合	7.1%	7.0% (前年比 p=0.82)	8.0% (前年比 p=0.0029)
治験	1.0%	0.7%	1.00%
保険診療	4.9%	3.7%	6.30%
適応外使用/その他	0.4%	0.2%	<0.1%

また、エキスパートパネルにかかる時間的負担について、2023 年、2024 年に続き 2025 年にも各中核拠点病院、拠点病院、連携病院について 1 症例当たりの所要時間（平均）の情報を収集した。2023 年における集計結果では 1 症例あたりにかかる平均所要時間は中核拠点病院で 62.7 分、拠点病院で 98.1 分であり、2024 年に行った集計でも 1 症例あたりにかかる平均所要時間は中核拠点病院で 69.2 分、拠点病院で 96.0 分、連携病院では 77.0 分であった。2025 年の調査では、中核拠点病院で 62.4 分、拠点病院で 84.8 分、連携病院では 68.1 分であり、日本臨床腫瘍学会が 2022 年に公表した 63 分から経年的に比較しても大きな変化はなかった。最も大きい負担は事前準備であり、時間的負担のおよそ 6～7 割を占めていた。

	日本臨床腫瘍学会調べ	2023年集計**			2024年集計***			2025年集計****			
施設	中核拠点 12施設	中核拠点 13施設	拠点 32施設	拠点 30施設	連携 14施設	中核拠点 13施設	拠点 29施設	連携 15施設	中核拠点 13施設	拠点 29施設	連携 15施設
事前準備	36分	37.1分	55.5分	48.8分	60.3分	40.4分	43.4分	52.4分	40.0分	40.0分	40.0分
ブレエキパネ	7分	10.6分	23.1分	10.6分	14.8分	30.0分	10.0分	12.1分	10.0分	10.0分	12.1分
エキスパート パネル	6分	4.5分	9.4分	4.0分	6.0分	7.5分	4.5分	8.4分	4.5分	8.4分	8.8分
報告書作成	14分	13.0分	17.5分	9.2分	20.8分	11.8分	14.0分	19.7分	14.0分	19.7分	14.3分
合計	63分	62.7分	98.1分	69.2分	96.0分	77.0分	67.4分	84.8分	68.1分	68.1分	68.1分
1回のEPあたりの 平均実施例数	23.2件 (12-60)	7.4件 (2-20)	21.0件 (13-35)	8.2件 (0-20)	4.1件 (0-15)	20.1件 (10-30)	11.3件 (2-20)	4.1件 (0-12)	4.1件 (0-12)	4.1件 (0-12)	4.1件 (0-12)
連携施設数			12.1 (1-25)	2.8 (0-17)	0	12.7 (2-25)	2.8 (0-10)	0			

(2) 薬剤到達率向上を目指したオンタイムでの治験情報共有システム構築について、EDC の構築を完成し、アカデミア・アセンブリにおいて治験情報の共有を継続した。本システムはアカデミア・アセンブリ参加者がリアルタイムにアクセス可能なものとして構築されている。また、アカデミア・アセンブリにおいて毎月行われる定期会議において、2026 年 3 月までに 25 回 36 事例について事例検討を行い、アカデミア・アセンブリにおける共通認識を確認し共有した。AI 等を活用した EP およびデータ入力の効率化に資するデータベース構築のためのレジストリー研究を 2024 年 10 月より登録開始し、2026 年 2 月に 504 例の登録をもって完遂した。うち 238 例にエビデンスレベル A/B/R 症例が含まれている。

(3) 提言書の作成

1 年次、2 年次は、(1) にある通りアンケート調査を行い、課題の抽出を行った(担当：内藤、角

南、今井、小山、吉野)。また、全国すべての中核拠点病院、拠点病院および一部の連携病院（主としてEP実施施設）からなるアカデミア・アセンブリを組織し、毎月アカデミア・アセンブリ全体会議を開催し、EP実施やCGP検査に関する情報の共有、問題点の議論、事例検討、アンケート調査結果の共有などを行っている。アカデミア・アセンブリにおいて提言書作成のためのアンケート調査を実施した(担当：内藤、角南、今井、小山、吉野)。提言書は原案を作成し、関連学会や患者団体への回覧、パブコメ募集が予定されている。

(4) 中核拠点病院が行うCGMC研修のためのカリキュラム、シラバス、講義用スライドを作成するためのメンバーを選出し、2025年6月17日および6月18日にミーティングを行った。厚生労働科学研究費 がん対策推進総合研究事業「ゲノム情報に応じたがん予防にかかる指針の策定と遺伝子腫瘍に関する医療・社会体制の整備及び国民の理解と参画に関する研究」班(23EA1037)(研究代表：国立大学法人岡山大学 学術研究院医歯薬学域 臨床遺伝子医療学分野 臨床遺伝子医療学 教授 平沢 晃)と協同で遺伝性腫瘍に関する多遺伝子パネル検査(MGPT)についても教育資料に盛り込んだ。2025年9月にカリキュラム、シラバスおよび講義用スライドを完成した。2025年9月30日作成したカリキュラム、シラバスを中核拠点病院に配布した。(担当：内藤、角南、今井、小山、吉野)。

D. 健康危険情報

なし

E. 研究発表

1. 論文発表

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2. 学会発表

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F. 知的財産権の出願・登録状況（予定を含む。）

1. 特許取得
なし
2. 実用新案登録
なし
3. その他
なし

研究成果の刊行に関する一覧表

書籍

著者氏名	論文タイトル名	書籍全体の編集者名	書 籍 名	出版社名	出版地	出版年	ページ
なし							

雑誌

発表者氏名	論文タイトル名	発表誌名	巻号	ページ	出版年
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